



Challenge TB - Malawi

Year 2

Annual Report

October 1, 2015 – September 30, 2016

November 5, 2016

Cover photo: Engineer and Trainer for OIdelft Benelux, Anton Baas, unpacking and assembling an X-ray machine procured by CTB in the presence of CTB Country Director, Dr Anthony Abura (in red tie) and ICF/ECF/ACF team members during an initial X-ray training. Credit: Dr Seraphine Kaminsa

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List of Abbreviations and Acronyms

AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral therapy
ARV	Antiretroviral drug
ACF	Active Case Finding
ADB	African Development Bank
BOQ	Bill of Quantities
CDC	Centers for Disease Prevention and Control
CTB	Challenge TB
CI	Contact Investigation
CHAI	Clinton Health Access Initiative
CNR	Cases Notification Rate
CHSU	Community Health Sciences Unit
CEMED	Central Monitoring and Evaluation Division
BOQ	Bill of Quantity
DFID	Department for International Development
DHMT	District Health Management Team
DR-TB	Drug-resistant Tuberculosis
DOTS	Directly Observed Treatment Short Course Strategy
DRS	Drug Resistance Survey
DST	Drug Susceptibility Testing
DQA	Data Quality Assessment
DAPP	Development Aid from People to People
DTO	District TB Officer
EQA	Eternal Quality Assurance
EU	European Union
ERR	Electronic Recording and Reporting
ETA	Expected Time of Arrival
ECF	Enhanced Case Finding
ECSA	East, Central and Southern Africa Health Community
FAST	Find Actively Separate and Treat
GF	Global Fund to Fight AIDS, Tuberculosis and Malaria
FLD	First Line Drug
GLI	Global Laboratory Initiative
GoM	Government of Malawi
HCW	Health Care Workers
HIV	Human immunodeficiency virus
HTSS	Health Technical Support Services
HSA	Health Surveillance Assistant
IPT	Infection Prevention Therapy

ICF	Intensified Case Finding
IC	Infection Control
IEC	Information Education and Communication
IP	International Partner
IPC	Infection Prevention & Control
KNCV	Koninklijke Nederlandse Centrale Vereniging voor Tuberculosebestrijding
KPS	Karonga Prevention Study
LPA	Line Probe Assay
LTBI	Latent TB Infection
LQMS	Laboratory Quality Management System
LIMS	laboratory Information Management System
M&E	Monitoring and Evaluation
MDR-TB	Multi-Drug Resistant TB
MoH	Ministry of Health
MSF	Médecins Sans Frontières
MSH	Management Sciences for Health
NAC	National AIDS Commission
NSP	National Strategic Plan
NTP	National TB Programme
NTRL	National Tuberculosis Reference Laboratory
NICD	National Institute For Communicable Diseases
NFM	New Funding Model
ODPP	Office of the Director of Public Procurement
OR	Operation Research
OPD	Out Patient Department
PIU	Program Implementation Unit
PLHIV	People Living with HIV
PPM	Pooled Procurement Mechanism
PP	Private Provider
PSM	Procurement Supply and Chain Management
PSP	Pharmaceutical Strategic Plan
PMDT	Programmatic Management of Drug-Resistant TB
PEPFAR	President's Emergency Plan for AIDS Relief
PMU	Program Management Unit
QECH	Queens Central Hospital
RR-TB	Rifampicin-Resistant TB
TA	Technical Assistant
TB	Tuberculosis
TBCARE II	US – funded TB consortium led by URC
TWG	Technical Working Group
TBD	To be done

SLD	Second Line Drug
SNRL	Super National Reference Laboratory
SLMTA	Strengthening Laboratory Management Towards Accreditation
SLIPTA	Stepwise Laboratory Improvement Process Towards Accreditation
URC	University Research Corporation
USAID	United States Agency for International Development
USG	United States Government
UPS	Uninterrupted Power supply
TB IC	Tuberculosis Infection Control
WHO	World Health Organization
WB	World Bank
XDR TB	Extensively Drug Resistant Tuberculosis
Xpert	Xpert MTB/RIF rapid molecular test

1. Executive Summary

Challenge TB (CTB) is a 5-year project funded by United States Agency for International Development (USAID) and it runs from October 2014 through September 2019. In Malawi, CTB is being implemented by KNCV TB Foundation to support the National TB Control Programme (NTP) in reducing tuberculosis related mortality and morbidity. CTB is working through national and zonal levels to support 15 out of 28 districts in the country. The project was granted US \$ 6,010,360 to cover a one-year period from October 2015 to September 2016. The CTB activities are aligned with Malawi's revised National TB Strategic Plan (NSP 2015-2020) objectives namely:

1. Reduction of TB related mortality by 50% by the end of 2020 from the 2014 baseline.
2. Increase in Case Notification Rate (CNR) from 121 per 100,000 (2013) to 252 per 100,000 in 2020.
3. Increase treatment success rate for new smear positive TB cases from 84% in 2014 to 90% by the end of 2020.

To achieve its objectives, CTB Malawi focused on the following sub-objective areas: Enabling Environment, Comprehensive High Quality Diagnostics, Targeted Screening for Active TB, Infection Control, Political Commitment and Leadership, Comprehensive Partnership and Informed Community Involvement, Drug and Commodity Management Systems, Quality Data, Surveillance and M&E, and Human Resource Development.

Based on further discussion with the NTP some areas were considered of lesser priority for CTB as other International Partners (IPs) are engaged in these activities: ActionAid will be addressing awareness and improving Health seeking behavior for TB and HIV. With regards to Patient centered approaches, CTB will continue to look for opportunities to address this through ongoing capacity building.

The following are the key outcomes/results for APA2:

- 1. Good collaboration between CTB and NTP:** The collaboration between CTB and NTP staff has improved at all levels, which has resulted in quality implementation of activities where partners support one another. For example, CTB participates in NTP regular technical meetings where the status of workplans for both CTB and NTP are reviewed, challenges in implementation discussed and action plans developed.
- 2. Baseline Assessments:** CTB in collaboration with NTP conducted several baseline assessments during the year; 1) Assessment of the entire TB laboratory network by KNCV consultants in APA2 Q1; 2) The GeneXpert network was assessed regarding distribution, utilization, and functionality of the diagnostic platforms and 3) An assessment of all the CTB 15 priority districts and selected health facilities with regard to various aspects of TB control.
 - 1) The main findings and observations for the TB laboratory network assessment included as strengths: availability of TB microscopy services in many health facilities, adequate personnel in most of the laboratories, uninterrupted TB microscopy services and existence of proficiency testing program for Xpert laboratories. Challenges observed included inadequate coordinating role of the NTRL and the NTP in strengthening TB laboratory services, weak specimens referral systems causing underutilization of the existing laboratory capacity and long turnaround times, poor infrastructure especially at NTRL and in lower level laboratories, use of non-serviced biological safety cabinets, inadequate on-job training and retraining, interrupted Xpert services due to stock outs of cartridges, lack of maintenance contracts for major equipment, lack of regulatory documentation on the

laboratories including standard operating procedures, inadequate routine quality control and inconsistent external quality assessment program for TB microscopy. The gaps identified were translated into action items that were mostly implemented during APA2. CTB supported with the servicing of biological safety cabinets and MGIT960 machines, procurement of Xpert cartridges, training of lab personnel on TB microscopy and GeneXpert technology and strengthening the EQA program for TB microscopy through central and zonal level supportive supervisions. In year 3, CTB will extend to support district level supervisions and Global Fund will support infrastructure upgrade in peripheral microscopy sites.

- 2) The key findings of the national GeneXpert network assessment noted that the past implementation of the 44 Xpert machines in the country was poorly initiated without a formal strategy or implementation plan. As a result, the Xpert platforms were not placed at facilities with the necessary infrastructure to support testing, insufficiently maintained, and underutilized (~25%). Maintenance limitations leading to module and instrument failure included a lack of routine maintenance as suggested by the manufacturer, no annual calibrations, and no warranties to ensure services for the machines. The results and recommendations that followed guided the development of an action plan to establish a functional network. Actions outlined focused on; trainings targeting clinicians and lab staff to improved utilization of Xpert and its associated algorithms; development of a system for accurate forecasting and cartridge supply management, as well as the additional procurement of 4 machines with proper placement and installation. CTB also supported the placement and installation of 4 machines that were handed over from TB CARE II project. All of these activities were successfully implemented in Y2. Moving into year 3, the rollout of GXAlert has been planned, which will facilitate the process of monitoring the machines and reporting test results in real time.
- 3) The key findings of the district and site-level assessment in the 15 priority districts included as strengths: good management of expired drugs and ongoing expansion of TB/HIV integration in the facilities. Challenges included: poor documentation and use of old version registers in some sites, lack of Infection Prevention & Control (IPC) plans, unavailability of TB/HIV committees, about 75% of the Community Sputum Collection Points that had been established are non-functional. The recommendations made included: capacity building of patient attendants/wards clerks, TB officers, laboratory personnel on data collection tools, development of IPC plans, ongoing expansion of TB/HIV integration supported through joint supervision and mentorship, and support of zonal TB/HIV review meetings. These recommendations were followed up and implemented throughout the year.

3. Laboratory Network:

- a) **Renovation of National TB Reference Laboratory (NTRL):** The NTRL has been non-functional since September 2015. However as of November 2015, CTB supported the NTP with renovations necessary to restore routine culture and DST testing to reactivate the facility, which is expected to be completed by February 2017. Renovations completed include; (1) rehabilitation of the media preparation room, staining room and main culture laboratory, (2) replacement of cold room, (3) installation of air-conditioning units, (4) servicing and recertification of biosafety cabinets, (5) installation of UPS for biosafety cabinets, and (6) repairing the generator. CTB is currently renovating preparation and washroom areas as well as installing the necessary ventilation units to ensure the required 6-12 air exchanges per hour needed for the laboratory to have a safe work environment. The new ventilation system will

upgrade the to a WHO recommended High Risk TB containment laboratory; safe for handling TB specimens for culture and DST evaluations. Renovations to the NTRL are time-sensitive as the country prepares activities for the upcoming national Drug Resistance Survey (DRS), which is scheduled to start in APA3. In the meantime, to avoid interruption of services, CTB supported the deployment of staff to Mzuzu laboratory for processing the culture samples as well as to provide mentorship to the Mzuzu laboratory personnel as they implement culture and DST testing in their regional reference laboratory. Furthermore, CTB has engaged important players such as the GLI and ECSA to support NTRL and NTP staff for advanced international trainings. CTB also assisted in linking the NTRL with the Uganda SRL to assist with technical developments and proficiency testing required for external quality assurance

- b) Revision of National Laboratory Strategic Plan:** CTB supported a workshop in Salima with the aim of updating the National Laboratory Strategic plan. In attendance were Ministry of Health (MoH) Diagnostics Unit, NTP, MoH CEMED (Central Monitoring and Evaluation Division) and partners such as URC, Dignitas and CTB (CTB represented by the Country Director, Advisor Diagnostic Network and M&E Advisor). MoH Diagnostics Unit facilitated the workshop. The main outcome of the workshop was a draft National Laboratory Strategic Plan, which was printed and disseminated for a comprehensive review. A smaller team that includes CTB representation was further selected to finalize the document, which is expected to be completed in APA3.
- c) Revival of TB laboratory EQA programme:** CTB supported a workshop in Salima with the aim of updating the National TB Laboratory EQA guidelines. The purpose of updating the guidelines was to ensure that the guidelines provide a comprehensive framework for all TB diagnostic methods available in the country including Xpert MTB/RIF, culture and Drug susceptibility testing (DST). The EQA guidelines will be finalized, printed and distributed in APA3. CTB also supported onsite supervision by the NTRL to selected health facilities in the network. Supervision visits were conducted in all five zones through support from CTB. Five zonal EQA review meetings were also carried out in September. These meetings provided a platform where health facilities, Zonal TB Officers, Zonal Laboratory Supervisors and NTRL met to discuss overall laboratory performance with lab representatives. Following these meetings, action plans were developed to improve the quality of testing within all five zones. Activities outlined in the action plans will be implemented and assessed in APA3.

4. Capacity Building through trainings:

- a)** Since the baseline assessments revealed poor recording and reporting practices, trainings were conducted by both CTB and NTP in the zones to strengthen the appropriate use of recording and reporting tools. A total of 796 people (537M, 259F) were trained. The participants came from a variety of cadres including; clerks, patient/ward attendants, lab technicians/microscopists and TB officers. In departments (such as Out Patient Department (OPD), ART clinics etc.) that did not have the recording tools/registers, these were subsequently provided. The OPDs have now introduced Chronic Cough Registers (CCRs) to capture presumptive TB cases, which were initially missed opportunity. The use of the CCRs proved to have impact on case finding and early case detection.
- b)** The NTP and CTB identified key challenges in basic TB/HIV management training, where staff have not received refresher training for some years. We have since embarked on facility level training where 195 clinicians (142M, 53F), 136 nurses (39M, 97F) and 1,037 health surveillance assistants (HSA) (658M, 379F) were trained in all the 15 CTB priority districts. HSAs were trained in basic TB as they are a key for TB control in the Malawi Health System for Primary Health Care and they are also the frontline workers who screen, diagnose and initiate TB treatment. As a result of these trainings, these HCWs are now supporting TB activities in the facilities such as increasing awareness of TB in communities, enhancing early case detection and systematically

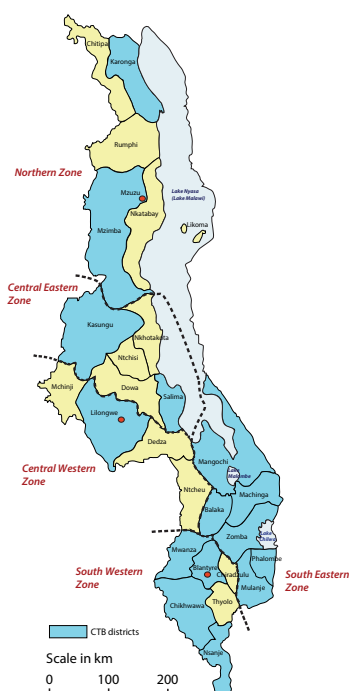
screening clients for TB. We expect to see the results of these trainings in Y3, such as increased identification of presumptive TB cases and improved use of GeneXpert.

5) ICF/ECF/ACF

In April 2016 CTB hired two ICF/ECF/ACF teams of five members each for Blantyre and Lilongwe Districts. These include an ACF Coordinator, Nurse Manager, Community Mobiliser, X-ray Technician and Laboratory technician. Draft Standard Operating Procedures (SOPs) and an implementation protocol were developed for phase one of two. Phase one includes the Intensified Case Finding (ICF) and Enhanced Case Finding (ECF) components. These focus on finding the cases in the ART clinic and OPD respectively. Phase two will focus on Active Case Finding (ACF) activities, which will be conducted in the community. Prior to implementation of ICF/ECF activities, the two teams were oriented by both NTP and CTB. Six health facilities (three in Lilongwe and three in Blantyre) were selected for ICF/ECF activities because of their high TB and HIV burden. CTB procured four GeneXpert machines and three of these have been installed and are in use in three facilities. The fourth machine is awaiting completion of renovation works at Ndirande health centre, whose laboratory was damaged due to a power fault. In Q4 training was organised and implemented in two sessions on the use of portable digital X-ray equipped with CAD4TB software, which will be put to use in APA3. The protocols for ethical approval of implementation research for this new diagnostic technology (CAD4TB) are being formulated and will be submitted to NTP, followed by the PMU and the Ethics Committee of Malawi in Q1.

2. Introduction

Malawi is a low-income country in southern Africa. It shares borders with Zambia to the west, Mozambique to the south, southeast and southwest, and Tanzania to the north and northeast. The



government of Malawi is led by an elected president with a parliamentary system. The country is divided into three administrative regions; Northern, Central and Southern regions. These regions are further divided into 28 administrative districts. For operational purposes, the MOH has created 5 zones; South East, South West, Central East, Central West and North. Decentralization of TB Diagnosis and Treatment Centers as well as TB Registration Centers is an ongoing process by the MoH.

Malawi continues to be burdened by TB despite significant progress in TB Control since the country adopted the WHO recommended TB DOTS strategy at the beginning of the 1990s. The high HIV prevalence and the resulting high prevalence of TB/HIV co-infection have contributed to the health concern situation in Malawi. In 2013, 56% of the notified cases of TB were co-infected with HIV (NSP 2015-2020). Recently, the country conducted its first prevalence survey, which revealed that the prevalence of TB in the general population is 451/100,000.

The goal of the recently revised National Strategic Plan (2015-2020) is to reduce tuberculosis related morbidity and mortality by 75% by the end of 2025 compared to the 2014 baseline. KNCV TB Foundation is a partner which is supporting the NTP in reaching this goal through the CTB Project which is a 5 year USAID project. The project funding is US \$ 6,010,360 in APA2, which started in October 2015 and ended September 2016. It

provided support at national and zonal levels for 15 out of 28 districts in Malawi, which are highly burdened with TB and HIV. Furthermore, the project supported national level activities by the NTP that included External Quality Assurance (EQA), laboratory supervision, GeneXpert, key laboratory renovations and procurements, district level trainings and mentorship. CTB scope of work for APA2 is shown in Table 2.

Table 1: CTB Districts by population

15 CTB Districts	2016 Population
Mzimba	1,161,858
Kasungu	858,782
Salima	432,069
Lilongwe	2,588,808
Mangochi	1,053,585
Machinga	627,399
Zomba	820,309
Blantyre	1,328,245
Mulanje	579,818
Phalombe	383,273
Chikwawa	549,706
Nsanje	288,581
Balaka	409,420
Mwanza	105,743
Karonga	348,110
Total	11,535,706

Table 2: Priority technical areas and scope of work for APA 2

Objective 1	Objective 2	Objective 3
Improve quality of TB services in terms of access and service utilization for both clinical and diagnostic services using a patients centered approach	Prevention of transmission and disease progression	Strengthened TB platforms
Sub Objectives	Sub Objectives	Sub Objectives
1. Enabling environment 2. Comprehensive high quality diagnostic network 3. Patient centered care and treatment	4: Targeted screening for active TB 5. Infection Control 6. Management of latent TB infection	7. Political commitment and leadership 8. Comprehensive partnerships and informed community involvement 9. Drug and commodity management systems 10. Quality data, surveillance and M&E 11. Human resource development
Intervention Areas	Intervention Areas	Intervention Areas
1.1 Provision of services according to national guidelines for all care providers and risk groups 1.2 Demand side: Community empowered, especially among risk groups 1.3 Demand side: Health seeking behavior improved for types of services 1.4 Provider side: Patient centered approach integrated into routine TB services for all care providers for a supportive environment 2.1 Access to quality TB diagnosis ensured 2.2 EQA network for lab diagnostics & services functioning 2.3 Access to quality culture/DST ensured 2.4 Access, operation and utilization of rapid diagnostics (i.e. Xpert)	4.1 Contact investigation implemented and monitored 4.2 TB social determinants identified, appropriate interventions designed, implemented and monitored 5.1 Compliance with quality TB-IC measures in health care, community and congregate settings ensured 5.2 TB surveillance among HCW ensured 6.1 LTBI diagnosis and treatment among high risk groups ensured	7.1 Endorsed, responsive, prioritized and costed strategic plan available 7.2 In-country political commitment strengthened 7.3 Leadership and management competencies and capacities of NTPs ensured 8.1 National partnership and coordinating bodies functioning with appropriate representation and capacity 8.2. Global Fund grant ratings improved 9.1 Well-functioning procurement and supply chain management system in place 10.1 Well-functioning case or patient-based electronic

<p>ensured for priority populations</p> <p>2.5 Laboratory information management system operational and utilized</p> <p>2.6 Expedient laboratory specimen transport and results feedback system operational</p> <p>2.7 Bio-safety measures in laboratories ensured</p> <p>3.1 Ensured intensified case finding for all risk groups by all care providers</p> <p>3.2 Access to quality treatment and care ensured for TB, DR TB and TB/HIV for all risk groups from all care providers</p>		<p>recording and reporting system is in place</p> <p>10.2 Epidemiologic assessments conducted and results incorporated into national strategic plans</p> <p>11.1 Qualified staff available and supportive supervisory systems in place</p>
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3. Country Achievements by Objective/Sub-Objective

Objective 1. Improved Access

Sub-objective 1. Enabling environment

1.1 Provision of services according to national guidelines for all care providers and risk groups

For startup activities, CTB conducted two assessments on availability of services in the 15 CTB priority districts and Gene Xpert platform jointly with the NTP in order to determine baseline information. This resulted into recommendations, which were translated into activities.

Additionally, CTB supported the revision and updating of various guidelines, (e.g. community screening guidelines, MDR guidelines, IPC guidelines) recording and reporting tools and CTB also supported the reinvigoration of the national review meeting, which had not taken place for many years due to unavailability of funding. Furthermore, CTB supported trainings on national TB guidelines for HSAs, nurses and clinicians in Management of TB.

1.2 Demand side: Community empowered, especially among risk groups

CTB advertised for a local organization to map, assess and engage existing Community Based Organizations (CBOs), Civil Society Organizations (CSOs), and Non-Governmental Organizations (NGOs) active in the 15 CTB priority districts in collaborative TB/HIV activities. Terms of reference were developed and advertised in the local newspapers which led to the shortlisting and interview processes. A sub contract will be given shortly and work will commence after approval in quarter 1 of year 3.

Key Results

- 1. Central level Review Meetings:** These were attended by National Level staff, Zonal Supervisors and District TB Officers. Main findings were that many areas of the program had gaps including recording and reporting, patient management at facility level, limited knowledge and capacity amongst staff, poor linkage between CSCPs and health facilities. NTP has requested ongoing support for these biannual meetings from CTB and other partners.



From left: Zonal Radiologist Supervisor (North Zone), NTP Data Manager, CTB Zonal Advisor, CTB M&E Advisor, Mzuzu District TB Officer during a baseline assessment in March 2016 at Mzuzu Central hospital

- 2. Baseline Assessment:** Major findings across all 15 CTB districts were: good collaboration between TB and HIV activities at facility level even though the mode of integration varied from one-stop shop (where all TB and HIV services are provided under one roof) to referral integration (where a TB patient will be referred to HIV/ART clinic for an HIV test/ARVs respectively); availability of staff managing TB services; availability of recording and reporting tools in the facilities; presence of partners to support the districts and good management of drugs in most of the facilities. Some of the weaknesses identified included; lack of knowledge about TB among health care workers; only 28% of the assessed facilities are IC certified; lack of IPC plans and poor documentation of the recording tools (registers), 75% of the CSCPs that had been established are non-functional.
- 3. Engagement of Private Providers (PPs)** in the TB control program is one way of increasing TB cases. In view of this, CTB supported NTP to organize a meeting for PPs to discuss their involvement in TB services in Malawi. The meeting identified challenges, which need to be addressed for proper coordination between PPs and NTP. Following this discussion, CTB developed a PP mapping tool and shared it with various PPs for their completion. The tool assesses who the PPs are, where their geographic area is, what they do and what services they would require the NTP/CTB to support them with. As a follow up to this mapping exercise, CTB will support NTP in following up the activities to be implemented.
- 4. Strengthening HSA Engagement;** HSAs provide the linkage between volunteers in CBOs, community services and health facilities. CTB provided technical support in training 1037 HSAs (658M, 379M) in basic Management of TB. Following baseline assessment findings, a total of 796 HCWs (537M, 259F) consisting of ART clerks, Ward clerks, TB Officers, laboratory technicians, microscopists were trained in recording and reporting tools. Furthermore, 331 (180M, 151F) nurses and clinicians were trained in Management of TB. As a result of these trainings, knowledge and skills were enhanced which resulted in introduction of recording tools (e.g. chronic cough registers) in facilities where they were not available and enhancement of systematic TB screening.

Note that the results being reported on year 2 for all the indicators (except where specified) are for October 2015-June 2016. Data for July-September 2016 is currently being collected through joint TB/HIV supervision and CTB will report it in Q1 APA3.

#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y2	Y2
1	1.1.1. % of notified TB cases, all forms, contributed by non-NTP providers (i.e. private/non-governmental facilities)	<p>Description: Proportion of TB cases (all forms) reported by non-NTP providers (i.e. private/ non-governmental facilities)</p> <p>Indicator Value: Percent</p> <p>Level: National and Challenge TB geographic areas</p> <p>Numerator: Number of all TB cases (bacteriologically confirmed + clinically diagnosed; includes new & relapse cases) reported by non-NTP providers in the past year.</p> <p>Denominator: Total number of TB cases (bacteriologically confirmed + clinically diagnosed; includes new & relapse cases) reported by both NTP and non-NTP providers in the past year</p>	3% (415/13,787 in CTB districts) (2015)	5%	<p>CTB Areas: 4% (356/9,931)</p> <p>National: 3% (356/12,112)</p> <p>All private providers are in CTB area</p>
2	1.1.2: % of case reporting by private providers that also provide treatment outcomes for TB patients	<p>Description: Proportion of case-reporting by private providers that also provide treatment outcomes for TB patients</p> <p>Indicator Value: Percent</p> <p>Level: National and Challenge TB geographic areas</p> <p>Numerator: Number of case-reporting private providers that also provide treatment outcomes for TB patients</p> <p>Denominator: Total number of case-reporting private providers in the area</p>	100% (2015)	100%	<p>100% (7/7)</p> <p>(All 7 private hospitals/clinics are in CTB area)</p>

Sub-objective 2. Comprehensive, high quality diagnostics

In year 2, CTB initiated renovations of the NTRL, the revision of National TB Laboratory Strategic Plan, and the development of a comprehensive External Quality Assurance (EQA) guideline. Additionally, CTB

provided support for in-country and international trainings/workshops to build the laboratory technical capacity of national staff. Specific trainings and workshops attended are listed in Table 2. AFB microscopy trainings (ZN method), GeneXpert trainings, TB culture and identification training in South Africa and Uganda Training of NTRL staff on TB drug susceptibility testing in Uganda, Advanced Maintenance training on GeneXpert technology in France, the GLI Africa Workshop on TB laboratory diagnostic network strengthening in Uganda, and the CTB Laboratory Capacity Building workshop in Netherlands) . An assessment of the GeneXpert Network was conducted that revealed key focus areas for technical development and improvement. Furthermore, CTB procured various laboratory equipment and supplies, which included 4 GeneXpert machines, 32 backup power systems for GeneXpert machines, 25 iLED Microscopes with solar power capacity, 2 digital X-ray machines with CAD4TB software, 21,000 GeneXpert cartridges, and supported printing of recording and reporting tools. Furthermore CTB also supported the installation of 17 Biosafety cabinets and servicing of 27 existing cabinets. Finally, CTB continues to provide supportive technical supervision from the in-country CTB Diagnostics Advisor. Additional support by ECSA-HC and Uganda SNRL included provision of proficiency panels for AFB microscopy, culture and DST as well as training of the NTRL quality officer on Quality Management Systems in Uganda.

Table 2: Laboratory trainings and workshops

Name of training	Date of training	Venue	Total trained	Information dissemination/sharing with the lab network	Impact of trainings on lab program
Training of NTRL staff on TB drug susceptibility testing	2 -13 Nov 2015	ACILT South Africa	2 (2M, 0F)	Training report shared with NTP and other NTRL staff	No demonstrated impact those trained were transferred to another lab prior to re-opening of the NTRL
Training of NTRL staff on TB culture and identification	18 – 29 January 2016	ACILT South Africa	3 (3M, 0F)	Training report shared with MOH, NTP, NTRL, KNCV and URC	Improved technical capabilities of NTRL staff to perform TB culture and identification
Basic training on AFB microscopy (ZN method)	30 May – 17 June 2016	Chiradzulu, Malawi	24 (18M,6F)	Training report shared with MOH, NTP, NTRL, zones and districts lab managers	-Opening of 13 new microscopy sites in Central East Zone (8 in CTB area) -Improved and standard skills to perform microscopy
Basic training on AFB microscopy (ZN method)	15 Aug-2 Sept 2016	Zomba, Malawi	23(19M,4F)	Training report shared with MOH, NTP, NTRL, zones and districts lab managers	-Uninterrupted microscopy services in sites that initially had a single microscopist because another microscopist was trained -Improved and standard skills to perform microscopy
Training of NTRL and Mzuzu staff on TB drug susceptibility testing	23 May – 10 June 2016	Kampala Uganda	4 (4M, 0F)	Training report shared with MOH, NTP, NTRL, KNCV and URC	-Adequate number of staff that can perform quality DST - Improved technical capabilities of NTRL staff to perform DST -Improved work flow at Mzuzu lab -Improved collaboration and relations with SRL Uganda

Name of training	Date of training	Venue	Total trained	Information dissemination/sharing with the lab network	Impact of trainings on lab program
					-Change in work behavior and commitment from NTRL staff
Advanced training on GeneXpert technology	22 – 24 June 2016	Cepheid, Mauren-Scopont France	3 (2M,1F)	Training report shared with MOH, NTP, NTRL and KNCV Information was also shared during user trainings in August 2016	-Improved technical capabilities of NTRL and CTB staff to troubleshoot GeneXpert faults within the network -Reduced equipment downtime -Enhanced working relationships between NTRL and CTB diagnostics network advisor -Improved training curriculum for GeneXpert technology -Empowered NTRL with improved ownership of the GeneXpert network
Training on TB Culture and Identification	5-23 September 2016	Kampala, Uganda	2 (1M,1F)	Training report shared with MOH, NTP, NTRL and KNCV	-Resulted in adequate number of staff that can perform TB culture at Mzuzu lab - Improved technical capabilities of Mzuzu lab staff to perform TB culture -Improved work flow at Mzuzu lab
GeneXpert initial training	15-19 August 2016	Zomba and Mzuzu, Malawi	33 (26M, 7F)	Training report shared with MOH, NTP, NTRL, zones and districts lab managers	-Uninterrupted Xpert services in sites that initially had a single user -Improved and standard skills to perform Xpert tests -Better knowledge and skills of Xpert sites to perform routine GeneXpert maintenance -Minimal errors in certain sites that initially had high error rates
CTB Laboratory Capacity Building workshop	27 June – 2 July 2016	The Hague, Netherlands	2 (2M, 0F)	Training report shared with MOH, NTP, NTRL and zones	-Expanded knowledge in key areas of TB laboratory development and strengthening -Stronger linkages with other CTB countries -Improved work-plan for NTP and CTB -Stronger working relationship between NTRL manager and CTB diagnostic network advisor -Inculcate a sense of good laboratory practice

Name of training	Date of training	Venue	Total trained	Information dissemination/sharing with the lab network	Impact of trainings on lab program
GLI Africa Workshop on TB laboratory diagnostic network strengthening	19 – 21 July 2016	Kampala Uganda	1 (1M, 0F)	Workshop report shared with MOH, NTP, NTRL and zones	Expanded knowledge on GLI Africa and other key areas of TB laboratory development and strengthening -Stronger linkages with other stakeholders -Further inculcate good laboratory practice

Key Results

1. CTB supported the NTP with renovating the NTRL in order to reactivate routine culture and drug susceptibility testing services. The planned renovations were completed except for the upgrading of the laboratory to a BSL3 containment.
 - a. Culture and DST services are still provided in-country due to backup testing at Mzuzu TB regional laboratory
 - b. The ongoing work at NTRL was assessed by consultants from Uganda SNRL, National Institute for Communicable Diseases (NICD) South Africa, ECSA-HC and Air Filter Maintenance Service (AFMS) and recommendations were made that are being addressed in the additional works that will be completed by February 2017.
2. A draft National Laboratory Strategic plan was developed.
 - Draft National Lab Strategic Plan to be finalized by a smaller team including CTB staff
3. EQA program for microscopy was revived through support from CTB
 - Draft EQA guidelines are in place and being used;
 - Onsite supervision was conducted by central and zonal levels.
4. Improved technical capacity for the staff at NTRL and Mzuzu regional lab due to participation in basic trainings offered in South Africa and Uganda.
5. Improved coordination of the TB laboratory network by the NTRL.
6. No interrupted Xpert testing due to power blackouts or cartridge stock-outs.



Replacement of cold room at NTRL (Left: Old cold room, Right: new cold room)

#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y2	Y2
1.	2.1.2. A current national TB laboratory operational plan exists and is used to prioritize, plan and implement interventions.	<p>Description: This indicator measures whether or not a country has a defined TB laboratory operational plan (work plan) within the larger National TB Strategic Plan or National Laboratory Strategic Plan. The country and partners use the operational plan to design and implement priority activities to strengthen TB diagnostic services and the network for TB control.</p> <p>Indicator Value: Score based on the following: 0= Operational plan not available 1= Operational plan available 2= Operational plan available and follows standard technical and management principles of a quality work plan required for implementing the necessary interventions to build and strengthen the existing TB laboratory network (reference: "Practical Handbook for National TB Laboratory Strategic Plan Development"; http://www.stoptb.org/wg/gli/assets/documents/Lab_Strategic_Handbook.pdf) 3= Operational plan available and meets annual implementation targets</p>	0	1	1
2	2.2.2. #/% of laboratories showing adequate performance in external quality assurance for smear microscopy	<p>Description: Proportion of laboratories enrolled in External Quality Assessment for smear microscopy</p> <p>Indicator Value: Percent Level: National and Challenge TB geographic areas Numerator: Number of laboratories enrolled in EQA for smear microscopy Denominator: Total number of laboratories performing smear microscopy</p>	91% (61/70 National) Apr-Jun 2015	>95%	<p>National: 56 Facilities were assessed CTB Areas: Of the 56 facilities, 41 are in CTB area. The following laboratories showed adequate performance: National: 79% (44/56) CTB Area: 80% (33/41) Currently, there are 297 laboratories providing TB microscopy at national level. But since the EQA program had been</p>

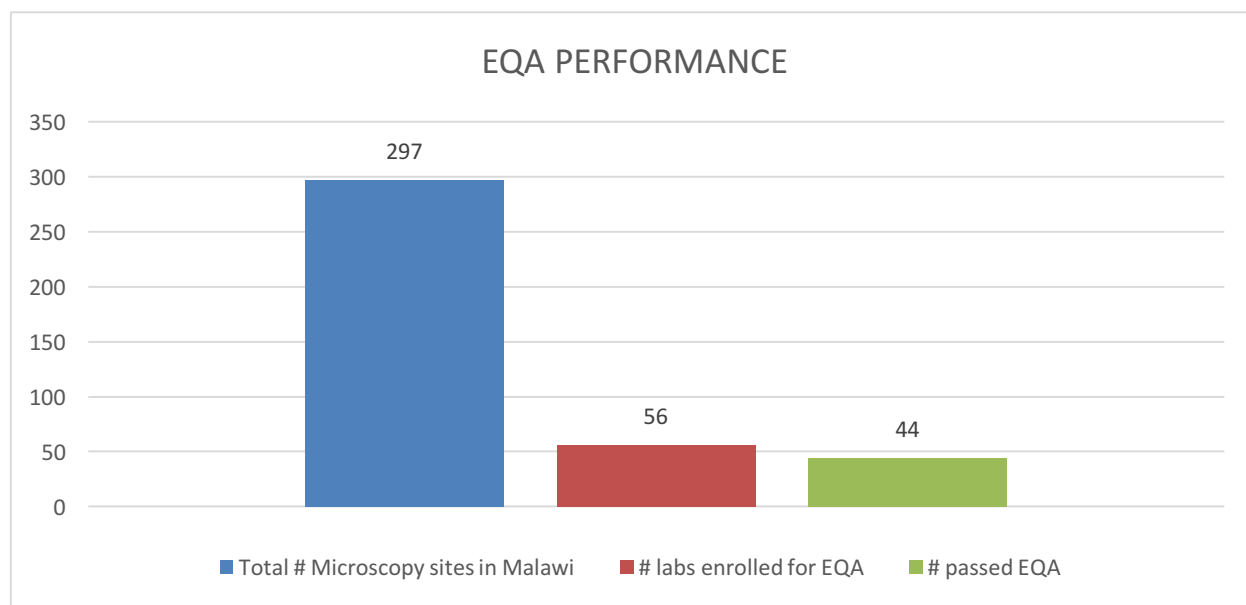
#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y2	Y2
					dormant for some time, they have not been able to assess all the 297 facilities in one year. Now with the revision of EQA guidelines and the support CTB is providing, more labs will be assessed.
3	2.2.4. #/% of laboratories showing adequate performance in external quality assurance for DST	<p>Description: Performance of EQA is just as important as having EQA established. This indicator measures the percent of laboratories enrolled in EQA for smear microscopy that successfully passed EQA in the last reporting period.</p> <p>Indicator Value: Percent Level: National and Challenge TB geographic areas Numerator: Number of laboratories that successfully passed EQA for smear microscopy Denominator: Total number of laboratories enrolled in EQA for smear microscopy</p>	1	2	<p>50% (1/2)</p> <p>Both cDST laboratories are in CTB area. The lab that is functional is Mzuzu reference lab. The NTRL is currently being reactivated</p>
4	2.2.6. Number and percent of laboratories performing C/DST that are implementing a laboratory quality management system (LQMS)	<p>Description: This indicator measures the percentage of TB reference laboratories in the country that are implementing a quality management system for continuous improvement of all aspects of laboratory operations to assure accuracy and reliability of testing, disaggregated by national and intermediate levels. Provide a score/rating for every reference laboratory implementing LQMS, either the "GLI Stepwise Process towards TB Laboratory Accreditation" (scoring = phase 1-4) or SLIPTA/SLMTA for TB (scoring=stars 1-5).</p> <p>Indicator value: Number and percent (Reference: Laboratory Quality Management Systems Handbook; http://www.who.int/ihr/publications/lqms/en/) Numerator: Number of TB reference laboratories implementing a quality improvement program</p>	50% (1/2 National) 2015	100% (2/2)	<p>0% (0/2)</p> <p>NTRL does not have any stars (zero) under the SLMTA program whilst the Mzuzu reference laboratory has not been assessed</p>

#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y2	Y2
		Denominator: Total number of TB reference laboratories in the country Level: National and/or Intermediate			
5	2.2.7. # of GLI-approved TB microscopy network standards met	<p>Description: This indicator measures whether or not a country has met the 11 GLI-approved standards for the TB microscopy network. A CTB checklist is provided to assess fulfilment of the requirements for each standard. Identify numerically (1-11) which standard(s) have been met. (Reference: "TB Microscopy Network Accreditation: an assessment tool"; http://www.who.int/tb/laboratory/microscopy-network-accreditation-assessment-tool.pdf)</p> <p>Indicator value: Number Numerator: Total number of standards met (NE=not evaluated, 0=no standards have been met).</p>	4 standards	8 standards	6 standards met. The following standards have <u>not yet</u> been met: 1, 2, 5, 8, and 10
6	2.3.1. % of TB cases tested for RR-/MDR-TB	<p>Description: This indicator measures the percentage of bacteriologically confirmed TB cases that are tested for drug resistance and also have results recorded in the TB register (disaggregated by new and previously treated cases). Drug resistance testing includes phenotypic (culture DST) and genotypic (molecular DST by GeneXpert, LPA or other molecular technologies).</p> <p>Indicator Value: Percent Level: National and Challenge TB geographic areas Numerator: Number of bacteriologically confirmed TB cases that are tested for drug resistance and have results recorded in the TB register. Denominator: Total number of bacteriologically confirmed TB cases notified during the reporting period</p>	Baseline not available	TBD	It has been a challenge obtaining this data during the year mainly because of the paper-based system. Mid last year, this data was added to the current NTP data collection form and it is being collected during joint TB/HIV supervision. TB supervisors are not collecting it well (under-reporting). Following this problem, supervisors have been trained and this is expected to improve. The NTRL is undergoing some renovations and samples have been going to Mzuzu reference laboratory for processing. In due course, there has

#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y2	Y2
					been a hiccup of documentation. CTB will support the NTP to implement GxAlert, which will be more efficient and reliable in obtaining this data from APA3.
7	2.4.2. #/% of Xpert machines that are functional in country (stratified by Challenge TB, other)	<p>Description: Proportion of Xpert machines that are functional in country</p> <p>Indicator Value: Percent</p> <p>Level: National and Challenge TB geographic areas</p> <p>Numerator: Number of Xpert machines that are functional</p> <p>Denominator: Total number of Xpert machines.</p>	96% (48/50 National) 2015	100%	<p>National: 100% (51/51). Partners in Hope recently handed over a machine to NTP during the year hence 51.</p> <p>CTB area. 100% (37/37)</p> <p>Despite the machines being functional, some modules are not working. Below is the functionality according to modules:</p> <p>National: 91% 177/194.</p> <p>CTB Area: 90 % 128/142</p>
8	2.4.6. #/% of new TB cases diagnosed using GeneXpert	<p>Description: Proportion of new TB cases diagnosed using GeneXpert</p> <p>Indicator Value: Percent</p> <p>Level: National and Challenge TB geographic areas</p> <p>Numerator: Number of new TB cases diagnosed using GeneXpert</p> <p>Denominator: Total number of new TB cases</p>	6% (1,000 / 17,104) 2015	8%	<p>National: 5% (620/12,037)</p> <p>CTB area: 5% (526/9,931)</p>
9	2.5.1. Status of national LIMS	<p>Description: The country must have functional Laboratory Information Management System (LIMS).</p> <p>Indicator value: Score based on below:</p> <p>0=no electronic system for storing/sharing TB laboratory results;</p>	0	1	0

#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y2	Y2
		<p>1=an electronic system for one testing technique (i.e. Xpert or DST), but not used nationally and no reporting mechanism for returning results to the provider;</p> <p>2=an electronic system for one or more testing techniques and used nationally OR has a mechanism for returning results to the provider;</p> <p>3=an electronic system for one or more TB testing technique that is used nationally, reports to providers and can be used for routine surveillance</p> <p>Level: National</p>			
10	2.7.1. #/% of laboratories implementing (internationally recommended) national biosafety standards (stratified by laboratories performing culture, DST and Xpert)	<p>Description: This indicator measures proportion of TB labs implementing internationally recommended biosafety standards (stratified by labs performing culture, DST and Xpert). Note that this measurement requires operations research using a valid tool.</p> <p>Indicator Value: Percent</p> <p>Level: National and Challenge TB geographic areas</p> <p>Numerator: Number of TB labs implementing national biosafety standards</p> <p>Denominator: Total number of TB labs</p>	2 Reference laboratories + 30 GeneXpert platforms in CTB districts	2 Reference labs + 30 Xpert platforms in CTB districts	<p>National: 1 Reference laboratory + 51 GeneXpert platforms</p> <p>CTB Areas: 1 Reference laboratory + 37 GeneXpert platforms</p>

Graph 1 showing External Quality performance of laboratories



Sub-objective 3. Patient-centered care and treatment

The interventions and activities aimed at enhancing patient centered care and treatment were as follows during APA2:

- Develop framework and implement pilot interventions for addressing urban TB (clinics in poor urban settings);
- Develop and implement screening algorithm for prison populations in coordination with MSH/Dignitas;
- Implement a standard testing of all retreatment cases for MDR-TB using GeneXpert;
- Support strategic updating of TB in Prisons;
- Support the access to quality treatment and care for TB, DR-TB and TB/HIV in prisons;
- Hold TB/HIV working group meetings and together with the HIV department, revisit IPT policy, print and disseminate;
- Support development and implementation of roadmap for Childhood TB specific for Malawi.

Key results

1. Two ICF/ECF/ACF teams were hired in April 2016, to support the NTP in finding the missing cases in health facilities and the community. Teams comprising a coordinator, nurse manager, laboratory technician, X-ray technician and community mobiliser, supported 6 high-burden sites in Lilongwe and Blantyre. These teams strengthened TB screening in the ART clinics, introduced on-spot sputum sample collection in facilities where it had been non-existent and supported processing of sputum samples and x-rays. The community component (ACF) is expected to start in APA3.



ACF Nurse Manager, Elizabeth Chamwalira during a monthly review meeting at Kawale Health centre

2. CTB jointly with NTP conducted an assessment in the prisons and also involved prison authorities to hold some discussions regarding the support that NTP will provide. Following these discussions, trainings were conducted in 6 major prisons where a total of 90 prison staff (63M, 27F) were trained on TB. In addition to these trainings, mass screenings for prisoners will be conducted in APA3.
3. CTB supported a Childhood TB Benchmarking workshop with the aim of assessing childhood TB services in the country and it was found that Malawi scored 4 out of the 20 standards. Recommendations are being translated into action items in order for the country to improve its score.
4. During baseline assessments we conducted, we found that there were issues of documentation in the registers (whereby the HIV status would be missing on the TB register but yet recorded on the patient master card or vice versa). During supervision, data is collected using the TB register as source hence resulting in under-reporting. Because of this problem, CTB trained staff in the filling in of recording tools and we anticipate these numbers to increase both at national and CTB levels. Additionally, CTB areas cover a lot of districts with high volume of TB cases (9,931), hence matching the HIV status in the register and TB master cards will take a bit of time with the CTB Zonal Advisers providing support during mentorship visits and M&E team providing support through Data Quality Assessments (DQAs).

#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y2	Y2
1	3.1.1. Number and percent of cases notified by setting (i.e. private sector, pharmacies, prisons, etc.) and/or population (i.e. gender, children, miners, urban slums, etc.) and/or case finding approach	<p>Description: The number of TB cases all forms (i.e. bacteriologically confirmed plus clinically diagnosed, new and relapse) reported by the NTP disaggregated by setting (i.e. private sector, pharmacies, prisons, etc.) and/or population (i.e., gender, children, miners, urban slums, etc.) and/or case finding approach (ICF, ACF, CI). Private sector providers should be described according to context and case finding approach, for example, type of provider targeted (i.e., for profit medical clinics, pharmacists, informal providers, private hospitals, etc.)</p> <p>Indicator Value: Number and where available, percent Level: National and CTB geographic areas Numerator: Number of TB cases all forms (bacteriologically confirmed + clinically diagnosed; includes new and relapse cases) reported (by setting/ population/ case finding approach) nationally and in CTB geographic areas in the past year Denominator: Total number of TB cases (all forms) notified nationally and in CTB geographic areas</p>	13,787 (CTB Area) 2015	15,855	<p>CTB Area: ICF/ECF: 100% (9,931/9,931) The ACF component will commence in APA3</p> <p>Prison: 2% (158/9,931)</p> <p>Private sector: 4% (356/9,931)</p> <p>Children: 4% (938/9,931)</p>
2	3.1.4. Number of RR-TB or MDR-TB cases notified	<p>Description: Total number of bacteriologically confirmed MDR-TB cases diagnosed. Project should follow the MDR-TB/Xpert algorithm in country regarding whether Rifampicin-resistant TB cases (RR-TB) should be counted as confirmed MDR-TB. If a country's algorithm states that a RR-TB cases is automatically assumed to be MDR-TB (i.e. no further DST required), then RR-TB should be included in the number of confirmed MDR-TB cases diagnosed. Otherwise, RR-TB should be excluded until proven via further DST that the case is a confirmed MDR-TB case.</p> <p>Indicator Value: Number Level: National and Challenge TB geographic areas Numerator: Number of bacteriologically confirmed MDR-TB cases diagnosed during the reporting period</p>	106 (2014)	117	128 Cases notified at National level.

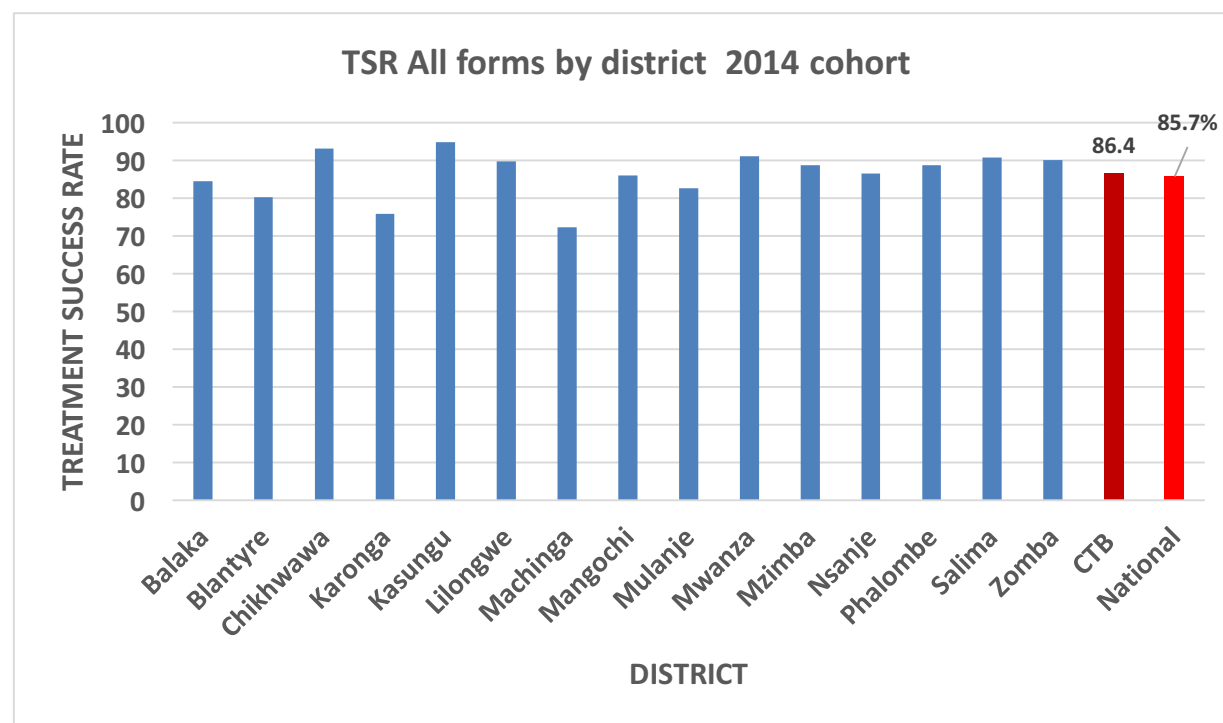
#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y2	Y2
3	3.1.8. % of TB cases (all forms) diagnosed among children (0-14)	<p>Description: This indicator measures proportion of TB cases (all forms) diagnosed in children 0-14 years of age. When childhood TB is a priority, being able to report on and measure changes in case notification by age group is important.</p> <p>Indicator Value: Percent Level: National and Challenge TB geographic areas Numerator: Number of TB cases (bacteriologically confirmed + clinically diagnosed; includes new & relapse cases) diagnosed in children 0-14 years of age in the past year. Denominator: Total number of all TB cases (bacteriologically confirmed + clinically diagnosed; includes new & relapse cases) reported the past year</p>	9.5% (1,310/13,787) (CTB Area) 2015	15%	<p>National: 8.4% (1,028/12,112)</p> <p>CTB Area: 9.4% (938/9,913)</p>
4	3.1.11. #/% of prisons conducting screening for TB with chest X-ray	<p>Description: Proportion of prisons conducting screening for TB with chest X-ray Indicator Value: Percent Level: National Numerator: Number of prisons conducting screening for TB with chest X-ray Denominator: Total number of prisons</p>	0 (National) 2015	0	0 This will be done in APA3
5	3.2.1. Number and percent of TB cases successfully treated (all forms) by setting (i.e. private sector, pharmacies, prisons, etc.) and/or by population (i.e. gender, children, miners, urban slums, etc.).	<p>Description: The proportion of a cohort of TB cases (all forms, bacteriologically confirmed and clinically diagnosed, new and relapse) registered in a specified period that were successfully treated, whether with bacteriologic evidence of success ("cured") or without ("treatment completed") by setting (i.e. private sector, pharmacies, prisons, etc.) and/or by population (gender, children, miners, urban slums, etc.) and/or risk population groups defined by national policy (IDUs, diabetics, prisoners, etc.). There may be overlap between settings and groups. Disaggregation by risk population is required in contexts where Challenge TB is providing treatment support for a specific group according to the annual work plan or in contexts where</p>	86% (12,182 / 14,097)	86%	<p>National: 86% (14,953/17,430), 2014 cohort</p> <p>CTB Area: 86% (12,210/ 14,127) 2014 Cohort</p> <p>This indicator cannot be disaggregated for treatment outcomes by setting and populations for the cohort under review. The revised R&R tools (introduced in April</p>

#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y2	Y2
		operations research allows for disaggregation and comparison across groups. Indicator Value: Percent Level: National and Challenge TB geographic areas Numerator: Number of new and relapse TB cases (all forms) registered in a specified period that were cured or completed treatment Denominator: Total number of new and relapse TB cases (all forms) registered in the same period			2016) include outcomes for PLHIV and children. The first disaggregated outcome data will be available for the patient cohort registered for TB treatment from APA3
6	3.2.4. Number of MDR-TB cases initiating second-line treatment	Description: The number of bacteriologically confirmed, clinically diagnosed or unconfirmed MDR-TB cases started on second-line treatment during the reporting period. Unconfirmed MDR-TB cases are those awaiting C/DST results. RR-TB may fall under confirmed or unconfirmed depending on the country's MDR-TB diagnosis algorithm. Indicator Value: Number Level: National and CTB geographic areas Numerator: The number of confirmed or unconfirmed MDR-TB patients started on second-line treatment in the reporting period	64 (WHO 2014 National)	80	This data is from January 2015 to June 2016 National: 88 CTB area: 62
7	3.2.7. Number and percent of MDR-TB cases successfully treated	Description: The proportion of confirmed MDR-TB patients successfully treated (cured plus completed treatment) among those enrolled on second line TB treatment during the reporting period (where applicable disaggregation by HIV status, XDR status). RR-TB may fall under confirmed MDR-TB depending on the country's MDR-TB diagnosis algorithm. Indicator Value: Percent Level: National and CTB geographic areas Numerator: Number of confirmed MDR-TB cases successfully treated (cured plus completed treatment) Denominator: Total number of confirmed MDR-TB patients enrolled on second line TB treatment during the reporting period.	53% (10/19) 2013 cohort	55%	National 53% (10/19) CTB areas: 40% (6/15) 2013 was a time when CTB was not there and most of the outcomes took place before CTB's implementation. Moving forward, CTB is supporting the monitoring of MDR patients through district review meetings.

#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y2	Y2
8	3.2.12. % of HIV-positive registered TB patients given or continued on anti-retroviral therapy during TB treatment	<p>Description: The purpose is to measure commitment and capacity of TB service to ensure that HIV-positive TB patients are able to access ART. This indicator measures people registered as HIV-positive who started TB treatment and who also started or continued on ART (i.e. recorded in ART register)</p> <p>Indicator Value: Percent Level: National and CTB geographic areas Numerator: All HIV-positive TB patients, registered over a given time period, who receive ART (are started on ART) Denominator: All HIV-positive TB patients registered over the same given time period.</p>	95% (6,490/6,852) CTB Area, 2015		<p>National: 96% (5,866/6,113)</p> <p>CTB area: 96% (4,773/4,959)</p>
9	3.2.13. % TB patients (new and re-treatment) with an HIV test result recorded in the TB register	<p>Description: The purpose is to assess how many TB patients know their HIV status, regardless of whether testing was done before or during TB treatment. In settings where HIV is driving the TB epidemic, all TB patients should be offered and encouraged to have an HIV test.</p> <p>Indicator Value: Percent Level: National and Challenge TB geographic areas Numerator: Number of TB patients registered over a given time period with an HIV test results recorded in the TB register. Denominator: Total number of TB patients registered over the same time period.</p>	93% (12,763 / 13,787) CTB Area, 2015	95%	<p>National: 94.9% (11,425/12,037)</p> <p>CTB area: 93% (9,254/9,931)</p>
10	TB Treatment Outcomes among registered new and relapsed TB cases who are HIV positive	Description: TB treatment outcomes of new and relapsed TB cases who are HIV positive	Not available		<p>Treatment outcomes were not collected by HIV status</p> <p>The revised R&R tools (introduced in April 2016) include outcomes for PLHIV.</p>

During the year, it was a challenge to meet some of the childhood TB targets such as proportion of notified cases amongst children and number of children initiated on IPT. This is a result of the following; there are challenges in implementation of Contact Investigation, limited capacity and knowledge to diagnose TB in children by health care workers, weak TB services in the Maternal and Neonatal Child Health settings and lack of review meetings due to prolonged period of non-funding for the NTP. CTB has supported the training of nurses in management of TB including for children and GF has also trained staff in contact investigation as well as resumed the review meetings which are a good forum for discussing progress.

Graph 2 showing the Treatment success rate for all forms of TB for CTB priority districts



Objective 2. Prevention

Sub-objective 4. Targeted screening for active TB

NTP had already begun implementation of CI activities since January 2016, following development of SOPs with Clinton Health Access Initiative (CHAI). In view of this, CTB supported the printing of the SOPs, job aides, diagnosis forms and appointment slips.

#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y2	Y2
1.	4.1.2 #/% of children (under the age of five) who are contacts of bacteriologically-confirmed TB cases that are screened for TB	<p>Description: The proportion of children (<5) who are contacts of bacteriologically-confirmed TB cases that are screened for TB (investigations for TB must be performed in accordance with existing national guidelines)</p> <p>Indicator Value: Percent Level: National and Challenge TB geographic areas Numerator: Number of children (<5) who are contacts of bacteriologically-confirmed TB cases that are screened for TB Denominator: Total number of children (<5) who are contacts of bacteriologically-confirmed TB cases</p>	Not available	Not available	The NTP data collection sheet was not capturing this information even though it is available in the recording tools. From APA3, CTB will start to report on this indicator after revision of data tools.
2.	4.2.3 % of confirmed TB patients by case finding approach (CI, ACF, ICF), by key population and location (ex, slum dwellers, prisoners) (Service cascade)	Please refer to indicator 3.1.1 above	Please refer to indicator 3.1.1	Please refer to indicator 3.1.1	Please refer to indicator 3.1.1

Sub-objective 5. Infection control

CTB in collaboration with NTP conducted the following activities under this sub objective:

- Build the capacity of IPC committees in 5 districts in TB-IC including scale up of F.A.S.T. in high risk environments
- Engage with relevant MOH and PEPFAR partners to develop a national policy, strategy and implementation plan for HCW screening and surveillance on TB as part of a wellness strategy
- Contract local/regional organization to assist the NTP in raising the level of awareness of TB among HCW and improved diagnosis and rapid treatment initiation

Key Results

1. KNCV Consultants Max Meis and Marleen Heus visited Malawi in April 2016 to build the capacity of TB-IC for IPC Committees. A workshop was conducted for 13 trainers (11M, 2F), followed by on-site workshops in 5 districts (Kasungu, Karonga, Mangochi, Lilongwe and Machinga) where the trainers trained a total of 49 participants. The workshops were organized and facilitated jointly by NTP IC Coordinator and CTB Technical Coordinator. During these workshops, a facility TB-IPC plan was developed to be scaled up to other districts.



Facility level discussion at Machinga District Hospital during TB IC assessment with Consultant Max Meis (standing), District TB Officer (in white shirt and khaki trousers) and CTB Zonal Adviser (sitting at the back in "End TB" White T-shirt).

Recommendations included: i. conduct targeted supervision, ii. monitor staff compliance with standards and iii. finalize draft documents such as Second Edition TB-IPC Guidelines, a costed 4-year plan, facilitators' Manual and facility work plans. Following this TA, supervisions have been conducted in Q3 for all these 5 districts and it was observed that the TB IPC plan had been finalized and orientations of the plan to health workers had commenced in some of the facilities. It was also observed that the District Health Management Team (DHMT) was committed to implementing IC activities.

2. CTB has planned to engage a consultant in APA3 to develop guidelines and strategy for HCW screening, detection and treatment; establish Wellness Centers for HCWs. The selection for this consultancy has been done in APA2 and the award is in process.

	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y2	Y2
1.	5.1.3 #/% of TB IC (i.e. FAST) certified health facilities	Description: This indicator measures the number and percent of health facilities implementing FAST (i.e. based on the criteria of FAST strategy - "Find cases Actively, Separate safely, and Treat effectively"). Note this measurement requires survey of facilities selected through lot quality assurance sampling and by using the 10-item modified CDC monitoring tool (health facility scoring YES on items 2, 4 and 5 is qualified as implementing FAST). Indicator Value: Percent Level: National and Challenge TB geographic areas Numerator: Number of TB IC certified health facilities in the area	0 (2015)	5	5
2.	5.2.1. Status of TB disease monitoring among HCWs	Description: This indicator measures the status of TB disease monitoring among HCWs in the country. Indicator value: Score based on below: 0=no policy/plan/ monitoring in place; 1=policy and scale-up plan for addressing TB among healthcare workers are enacted by the MoH; 2= monitoring program piloted or limited to certain areas; 3=annual reporting on TB among HCWs is available as part of the national R&R system Level: National	0	1	1
3	5.2.3 Number and % of health care workers diagnosed with TB during reporting period	Description: This indicator measures the percent of healthcare workers (HCWs) diagnosed with TB (all forms) annually (disaggregated by gender and age). This measurement may require a special study using a validated tool and/or methodology. Indicator Value: Percent Level: National and Challenge TB geographic areas Numerator: Number of HCWs diagnosed with TB (all forms) during past year Denominator: Total number of HCWs in the same year In countries where the NTP does not collect this indicator or is not willing to share the data, Challenge TB should document this challenge.	1.7% (CTB Baseline assessment)	<5% (refer to STEP table)	1.7 % (58/3,377). This was collected during the baseline assessment in CTB geographical areas.

Sub-objective 6. Management of latent TB infection

Malawi is implementing a component of LTBI through provision of IPT. Guidelines are available on provision of IPT for children exposed to TB patients and also a policy on use of IPT in HIV positive individuals for six months. CTB supported the printing of revised IPT recording and reporting tools for children.

#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y2	Y2
1.	6.1.11 Number of children under the age of 5 years who initiate IPT	Description: This indicator measures the status of implementing LTBI diagnosis and treatment strategies in the country. Indicator value: Score based on below: 0=no policy or practice in place; 1=policies have been developed/updated; 2=LTBI strategies piloted or implemented in limited settings; 3=LTBI strategies implemented nationally Level: National	2,770 (National, 2014)	2,900	National: 1,458 CTB Areas: 1,220 Score: 3

Objective 3. Strengthened TB Platforms

Sub-objective 7. Political commitment and leadership

The activities planned under this sub-objective in APA2 were as follows:

- Advocate for district funding through District council; participate in district executive committee meetings
- Advocate through the Parliamentary Committee for Health, Parliamentary Committee on HIV/AIDS and the Planning Department of MoH

Key results

As part of advocacy, CTB supported NTP by uploading key TB documents on the government website and a national newspaper. This was a pre-requisite for the World Bank funded 'TB in mines' project which was signed by the Malawi government and the World Bank. Additionally, the presence of CTB Advisers in the zones gives them an opportunity to participate in district executive committee meetings hence a good fora to provide ongoing advocacy and develop capacity of district TB officers (DTOs). CTB also supported the development of IEC materials, videos and airing of radio transcripts on TB-related messages.

#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y2	Y2
1	7.2.3 % of activity budget covered by private sector cost share, by specific activity	<p>Description: This indicator measures the proportion of CTB project activity budget covered by private sector cost share (if not monetary, will require estimation of costs) by specific activity.</p> <p>Indicator Value: Percent</p> <p>Level: Nationally for activities at national scale and in Challenge TB geographic areas for activities focused in specific geographic areas where Challenge TB is working.</p> <p>Numerator: Amount of private sector cost share covering CTB project activity during most recent fiscal year</p> <p>Denominator: Total CTB project activity budget plus private sector cost share amount during the year of assessment.</p>	0%	0%	0%

Sub-objective 8. Comprehensive partnerships and informed community involvement

The activities planned under this sub-objective in APA2 were as follows:

- **Strengthen the national platform led by NAC with participation of NTP, partners and civil society organization, faith based organizations to promote and advocate TB/HIV integration:** CTB met with National Aids Commission (NAC) where it was communicated that there is no national conference planned for this year. NAC also communicated that they have adequate funding for 2017 and would not need support from CTB.
- **Establish and support quarterly district-level platforms to coordinate TB and TB/HIV activities supported by the zones:** From March 2016, CTB Zonal Advisers and NTP Zonal supervisors commenced the support of district-level coordination meetings and these have been ongoing on a quarterly basis. Key issues arising in these meetings are challenges in TB sample transportation, poor TB screening among health workers, shortage of N95 masks and lack of training amongst health workers in Basic TB management. In order to address some of these challenges, the following activities have been conducted during APA2: a) Basic TB Management training for HSAs at district level, b) Clinicians and Nurses training in Management of TB c) A consultancy is planned for HCWs to improve screening, detection and treatment of staff with HIV and TB; establish wellness centers for HCWs and also to develop guidelines and strategy for staff wellness. The selection has been done and the award is in process.

#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y2	Y2
1.	8.1.3 Status of National Stop TB Partnership	<p>Description: This indicator measures the status of National Stop TB Partnership by using special questionnaire for collecting relevant country level data</p> <p>Indicator Value: The score based on below: 0= no National Stop TB Partnership exists 1= National Stop TB Partnership established, and has adequate organizational structure; and a secretariat is in place that plays a facilitating role, and signed a common partnering agreement with all partners; but does not have detailed charter/plan, and does not meet regularly/ produce deliverables;</p>	0	0	0
2	8.1.4 % of local partners' operating budget covered by diverse non-USG funding sources	<p>Description: This indicator measures the proportion of CTB project local partners' operating budgets covered by non-USG funding sources. A special questionnaire for collecting relevant country level data among CTB local partners is available.</p> <p>Indicator Value: Percent Level: Challenge TB geographic areas Numerator: Amount of CTB local partners' operating budgets covered by non-USG funding sources (TGF, WB, EU, ADB, DFID, private donations, investment income, other revenue, etc.) Denominator: Total operating budget of CTB local partners' operating budget (USG + non-USG sources) during the year of assessment.</p>	0	0	0
3	8.2.1. Global Fund grant rating	<p>Description: This indicator presents Global Fund TB grant performance rating results</p> <p>Indicator value: Score is based on the following: A1 Exceeds expectations A Good performance A2 Meets expectations B1 Adequate B2 Inadequate but potential demonstrated C Unacceptable Level: National</p>	B1	A1	B1

Sub-objective 9. Drug and commodity management systems

The intervention areas under this sub objective were as follows during APA2:

- **Provide high quality technical support to the NTP for the development of a procurement and supply chain management (PSM) strategic plan:** CTB provided technical inputs to the development of a five-year Pharmaceutical Strategic Plan (PSP) which was developed by the Health Technical Support Services (HTSS) Directorate of the Ministry of Health, with technical assistance from the USAID (DELIVER PROJECT).
- **Provide capacity building plan for health facilities at all levels; from National, Zonal to District, for better pharmaceutical management;** A workshop was conducted in Liwonde from 15-17 March 2016 where a total of 28 district pharmacy technicians were involved in identifying regional supply chain bottlenecks and ways to address them at local levels. Supply chain management training was also organized by the NTP, whereby 90 pharmacy personnel from health facilities and DHOs were trained on standard operating procedures of managing the supply of TB drugs.
- **Assist with the development of an efficient stock monitoring system, including drugs and lab supplies and look at the requirement for ancillary drugs to manage side-effects;** CTB PSM Advisor participated in a PSM national TWG in Q2 where stock-out, overstock, expiries and stock monitoring was discussed in the meeting. Quarterly supportive supervisions and TB drug spot checks were also carried out.
- **Assist the NTP with completing an assessment on the supply of Xpert cartridges and determine a plan for supply management:** Estimation of the required GeneXpert cartridges has been done by NTP laboratory team with support from CTB and GF and cartridges have since been procured. A new PSM Technical Advisor has recently taken over the role of providing technical assistance to all TB PSM related activities, including international procurement.

The first PSM Adviser left in May 2016, his successor arrived in September 2016. During this time interval, international procurement issues of TB were attended to by the Drug Management Logistics Officer of the NTP with technical supports from the Global Fund Technical Coordinator

#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y2	Y2
1.	9.1.1. Number of stock outs of anti-TB drugs, by type (first and second line) and level (ex, national, provincial, district)	<p>Description: This indicator should be used to report the number of stock outs of any type of TB drug at any level of the health system that results in interruption of treatment.</p> <p>Indicator Value: Number</p> <p>Level: This indicator should be reported at whatever level a stock out that results in interruption of treatment occurs.</p>	0	0	0

Sub-objective 10. Quality data, surveillance and M&E

The intervention areas under this sub-objective were as follows in APA2:

- **TA for developing a detailed costed development action plan for a (web based) electronic surveillance system (STTA):**
This activity was initiated in APA1 Q4 by consultants Job Van Rest and Nico Kalisvaart. During this visit they assessed the feasibility of implementing a case-based electronic recording and reporting (ERR) system. The consultants had a follow up visit in Q3 APA2 where CTB and NTP jointly had a workshop to define a roadmap and action plan for implementation of ERR system. In attendance were different stakeholders such as Baobab, MoH, NTP and CTB. Recommendations made were to build on the existing electronic system run by Baobab at Bwaila hospital which has a module on TB/HIV indicators. It was also recommended that an ERR TWG should be formed in order to follow up on the proposed steps.



Group discussion during ERR workshop with representatives from NTP, Baobab, MoH and CEMED

- **National consultation meeting on evidence and strategies to increase case-detection through: Contact investigation (CI), Intensified case finding (ICF) and Active case-finding (ACF):** CTB was introduced to the research network in Malawi and was able to appreciate the various TB focused research being done by the College of Medicine and other partners including the Liverpool School of Tropical Medicine with Wellcome Trust, the University of North Carolina and the London School of Hygiene and Tropical Medicine with the Karonga Preventive Study (KPS). CTB contributed to the review of abstracts, the preparation of the programme, payment for venue and participant costs and review of research priority areas for the Malawi NTP Operations Research Strategic Plan (2015) that are listed below:-Improving access, screening and diagnosis of tuberculosis, developing sustainable collaboration with all care providers for TB care and control, prevention and treatment of TB in persons living with HIV and treatment of drug susceptible and M/XDR-TB: optimal access, delivery and community participation.
- **Draft a first protocol for a DRS survey:** STTA was provided in November 2015 and February 2016 for the finalization of the protocol by KNCV Consultant, Dr. Eveline Klinkenberg. NTP conducted additional workshops to finalize the protocol. The finalization was dependent on the completion of the NTRL which is expected to be ready in APA3.

#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y2	Y2
1.	10.1.4. Status of electronic recording and reporting system	Description: This indicator measures the status of electronic recording and reporting (ERR) Indicator value: Score based on below: 0=R&R system is entirely paper-based; 1=electronic reporting to national level, but not patient/case-based or real time; 2= patient/case-based ERR system implemented in pilot or select sites (TB or MDR-TB); 3=a patient/case-based, real-time ERR system functions at national and subnational levels for both TB and MDR-TB;	1	1	1
2	10.2.1. Standards and benchmarks to certify surveillance systems and vital registration for direct measurement of TB burden have been implemented	Description: National TB surveillance system is certified based on WHO standards and benchmarks for TB surveillance and vital registration systems (for paper-based or electronic systems). For a country's TB surveillance systems to be certified as providing a direct measurement of TB cases and TB deaths, all 10 standards and their associated benchmarks (Part B, Section 1) should be met (source: Standards and Benchmarks for Tuberculosis Surveillance and Vital Registration Systems – Checklist and User Guide, WHO,	0	0	0

		2014). The country standards and benchmarks score will be monitored as a sub-indicator to track progress. Indicator Value: Yes/No			
3	10.2.3. DR-TB surveillance survey conducted/completed in the last 5 years	Description: DR-TB prevalence survey has been conducted/completed within the last five years Indicator Value: Yes/No	No	Yes	DR survey to be conducted in year 3. Lab is being renovated
4	10.2.6. % of operations research project funding provided to local partner (provide % for each OR project)	Description: This indicator measures the proportion of Challenge TB-supported operations research project funding provided to local partner(s), by each OR project. Indicator Value: Percent Level: Challenge TB geographic areas Numerator: Amount of operations research project funding provided to local partner by CTB during a year Denominator: Total Challenge TB operations research budget during the year of assessment.	0%	0%	0%
5	10.2.7. Operational research findings are used to change policy or practices (ex, change guidelines or implementation approach)	Description: For all Challenge TB-supported operation research projects implemented in a country, results of these projects are used to change policy or practices (ex. change guidelines or implementation approach). Relevant data are collected/ presented for each individual project by special report with qualitative details. Indicator Value: Yes/No Level: National	Not available	Not available	Not available

Sub-objective 11. Human resource development

The intervention areas under this sub-objective were as follows during APA2:

- **Update pre-service and in-service TB management training modules and assess current training status of HCWs by gender;**
CTB supported the NTP to update some of the guidelines and training materials that have been used for training of health care workers this year in TB infection Prevention and Control, MDR-TB, childhood TB and Community TB and Systematic TB screening in High Risk Groups. Trainings have been conducted with CTB and GF support. For childhood TB, the NTP received support from CHAI.



CTB Technical Coordinator, Dr Seraphine Kaminsa (in pink/black dress) collaborating with partners from NTP (in white shirt), DAPP (lady in middle) and WHO TB/HIV focal Person, Ishmael Nyasulu (right) during revision of TB IC guidelines

- **District and peripheral level TB management training and mentoring/on-the-job training:** CTB conducted these trainings jointly with NTP and the objective of the training was to equip district coordinators with knowledge and skills to plan, supervise, implement, monitor and evaluate activities of a district TB control program following WHO module.
- **Training of central and zonal supervisors:** Central and Zonal Supervisors were trained in March and 46 participants (38M, 8F) attended. The supervisors acquired knowledge and skills that has resulted in improved quality of integrated TB/HIV supportive supervision. The supervision tool was also revised. Supervisors were trained in TB/HIV mentorship skills so that they can mentor health workers during supervisions
- **Organize supportive supervision to zones for mentoring zonal TBOs in effective supervision:** CTB supported NTP in organizing a workshop that was aimed at revising NTP mentorship tools and the first mentorship was conducted. It is expected that these mentorship visits will result in improved quality diagnosis, treatment and care.
- **Quarterly zonal monitoring meetings:** The zonal monitoring meetings are embedded in the quarterly review meetings with participation of CTB Zonal TB Advisers and NTP Zonal Supervisors. Zonal level data is reviewed, challenges are discussed, recommendations made and action plans are developed.

#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y2	Y2
1.	11.1.1. Status of system for supportive supervision	<p>Description: This indicator measures the status of the system for supportive supervision</p> <p>Indicator value: Score based on below: 0=no supportive supervision guidelines developed and no consistent supportive supervision taking place; 1=supportive supervision plan developed, but not implemented systematically; 2=supportive supervision plan implemented consistently, including provision of written feedback to lower levels; 3=supportive supervision plan implemented consistently, feedback provided and evaluation of supervision plan conducted</p> <p>Level: National</p>	2 (National) 2015	3	3
2	11.1.2. % of planned supervisory visits conducted (stratified by NTP and Challenge TB funded)	<p>Description: The proportion of planned supervisory visits conducted (stratified by NTP and Challenge TB funded)</p> <p>Indicator Value: Percent</p> <p>Level: National and Challenge TB geographic areas</p> <p>Numerator: Number of planned supervisory visits conducted during reporting period</p> <p>Denominator: Total number of supervisory visits planned for the same period</p>	4	4	3 In 2015/16 only 3 Supervisory visits were done in January, April, and July as staff was not yet in position in October '15.
3	11.1.3. # of healthcare workers trained, by gender and technical area	<p>Description: This indicator measures the number of healthcare workers (which includes health facility staff, community health volunteers, laboratory staff, sputum transport technicians, community-based DOTS workers) trained, by gender and sub-objective. Training includes any in-person, virtual, or on-the-job training that is longer than half a day and for which curriculum is available. This indicator is interchangeable with 'Number of individuals trained in any component of the WHO Stop/End TB Strategy with USG funding', which USAID missions may have as a requirement for internal agency reporting.</p> <p>Indicator Value: Number</p> <p>Level: National and Challenge TB geographic areas</p> <p>Numerator: Number of HCWs trained during the reporting period</p>	N/A	N/A	<p>TB Management: Total Trained = 1,330 (819M, 511F) Quality Diagnostic: Total: 77 (61M, 16F) Data Tool Refresher Trainings Total: 796 (537M, 259F) Infection Control: 79 (66M, 13F) TB Supervisor Training: 53 (44M,9F)</p>

#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y2	Y2
4	11.1.5. % of USAID TB funding directed to local partners	<p>Description: This indicator measures the proportion of CTB annual funding directed to local partners</p> <p>Indicator Value: Percent</p> <p>Level: National. Although CTB may be working with local partners in specific geographic areas, the overall total going to local partners at any level should be included in the numerator and compared to the overall country budget.</p> <p>Numerator: Amount of CTB country project funding directed to local partners during the most recent fiscal year</p> <p>Denominator: Total CTB country project budget during the most recent fiscal year.</p>	0	0	0

4. Challenge TB Support to Global Fund Implementation

Current Global Fund TB Grants

Name of grant & principal recipient (i.e., Tuberculosis NFM - MoH)	Average Rating*	Current Rating	Total Approved/Signed Amount**	Total Committed Amount	Total Disbursed to Date
MWI-C-MOH	Rating not finalized & shared at present	Rating not finalized & shared at present	\$298,655,626 (both TB/HIV)	\$116,588,097	\$9,325,192 (both TB/HIV)
MWI-C-AA		N/A	\$29,287,078	\$14,428,496	\$4,688,527

* Since January 2011

** Current NFM grant not cumulative amount; this information can be found on GF website or ask in country if possible.

In-country Global Fund status - key updates, current conditions, challenges and bottlenecks

Key updates

The current GF grant managed by MOH is a joint TB/HIV grant with a majority of the allocated funds going to the HIV program. It is estimated that of the \$298 million, approximately \$ 38 million is specifically for TB activities. The second grant with Action AID as PR is focused on community based activities.

Procurement of Health Products for TB

- **NFM Procurement order for laboratory supplies and equipment:** Following procurement initiations that took place in March 2016, currently quotations are being sourced from Pooled Procurement Mechanism (PPM) for the following category of Health Products
 - i. Laboratory reagents for TB Case detection and diagnosis worth \$167,348
 - ii. Other consumables for TB Case detection and diagnosis worth \$ 14,693
 - iii. Microscopes for TB Case detection worth \$240,219
- **Procurement for FLDs and SLDs:** Shipments are in progress for all FLD and SLD that are expected to be received before end of October 2016. The next rounds of staggered shipments for FLD are expected to be received in March 2017; and in November 2016 and March 2017 for SLD. The ETA (expected time of arrival) for subsequent shipments after October may however change depending on the in-country stock situation in due course.

Procurement of Non-Health products for SLDs

- Program Implementation Unit (PIU) has been in the process of sourcing quotations from suppliers for non-health products such as motor vehicles and Mobile Digital X-ray. Quotations were sourced for Mobile Digital X-ray through a restricted tendering process, as per the guidance from the Procurement Oversight Agent of the MOH. However, there was only one potential supplier, with experience of supplying the equipment in the region, which responded to the bid. As a result the NTP is seeking a No Objection approval from Office of Director of Public Procurement ODPP for procurement of the equipment through a single-source procurement

method. Nutritional supplements for MDR-TB patients were provided during the first quarter of the year. For quarters 3 & 4 the supplements are under procurement process.

Implementation of programmatic Activities

Initially there was a delay in disbursement of funds but this has now been addressed through stakeholders meetings. The MoH has also created the PIU to mainly deal with administrative and financial issues so that NTP technical staff can focus on implementation.

With GF resource NTP has implemented various programmatic activities during the APA2. Some of the key programmatic activities conducted during APA2 were as follows:-

- Review meetings: Quarterly zonal level TB program review meetings in all five zones and TB laboratory system and EQA review meeting were conducted;
- Developed detail micro plan to accelerate the implementation of GF activities in the year. These activities were done in collaboration with CTB;
- Training: GeneXpert training for laboratory personnel in three rounds and PMDT training for various HCWs from north and south west zones. A total of 75 Laboratory personnel received training on GeneXpert diagnostic algorithms;
- Supportive Supervision: Supportive supervision on systematic TB screening at HFs, TB drugs spot check and TB data quality assessment.

Challenge TB involvement in GF support/implementation and any actions taken during Year 2

- CTB hired a PSM Advisor who reports to the NTP Program Manager and provides long term technical assistance on procurement for GF related issues;
- With financial support from CTB the first round assessment for renovation of infrastructure sites expansion were conducted in 28 district hospitals and three central referral hospitals. The final assessment report, bill of quantities (BOQ) and design will be communicated to GF to release the funds.
- CTB hired ACF teams who are supporting the NTP in finding the missing cases. These teams are being co-managed by both CTB and NTP but will eventually be under GF from APA3.
- CTB provided Technical Assistant from a consultant Dr Eveline Klinkenberg on the development of a Drug Resistance Survey protocol
- CTB is supporting the renovation of the NTRL in preparation for the planned DRS
- CTB has funded some GF activities whose funding was delayed such as Mentorship visits, assessment of facilities and national review meeting;
- CTB staff attended a work planning meeting with NTP supported by GF with the objective to share and harmonize GF and CTB work plan and improve coordination;
- CTB has supported the orientation of PSM supervisors in preparation for supportive supervision;
- CTB participated in a meeting with MOH to discuss PSM strategies and harmonization of procurement plan of TB and HIV;
- CTB attended a meeting with Action Aid and GF country team to finalize the GF budget;
- National stock status was prepared by NTP with support from CTB PSM Advisor. This data was used to determine quantities needed for procurement orders for 1st line drugs, 2nd line drugs, laboratory and infection control items such as UVGI fixtures;
- CTB PSM Advisor has been working on procurement of mobile X-ray vans budgeted in the GF grant and supported the NTP in all TB-related procurements;
- CTB Zonal TB Advisors participated in zonal review meetings and MDR-TB trainings during the year, which were supported by GF.

5. Challenge TB Success Story

Improving TB Case Finding

Fanny Kanjodo is both a former TB patient and a nurse at Police Hospital in Zomba. She suffered from TB symptoms for about five months before she was finally diagnosed. She attended the TB Training for nurses and clinicians organized by the USAID funded Challenge TB project, where she learned all about TB management. When she finished the course she vowed to improve TB screening and ensure that diagnosis is made early, in contrast to her own experience.

Fanny kept her word, after the training she mobilized clinical staff on TB active case finding activities at her facility and this included Systematic TB screening, triaging at the OPD/ART Clinic, ensuring that those who had TB symptoms had access to GeneXpert and referral for further diagnosis to the central hospital. Following this mobilization, Fanny and other health care workers reviewed the Chronic Cough Registers to assess the number cases that had been examined and ultimately diagnosed with TB. They found that there had been an increase of 60% in the number of presumptive cases identified in the third quarter when compared to first (16 in Q3, 10 in Q1). Of these, 62% (10/16) were as direct result of the mobilization she conducted. Furthermore, the proportion of people diagnosed with TB was 25% (4/16) - compared to 10% (1/10) in the first quarter.

Some of the significant activities currently being conducted at the facility as a result of Fanny's training are documentation in patient registers, TB Patients are now being followed-up, patient's weights are now recorded and the necessary adjustments to drug dosages are made as a result. Also a TB/HIV coordinating committee has been formed, a situation analysis has been conducted, gaps identified and an action plans developed.

It just goes to show that training one nurse can save lives and improve the health system.



Fanny assists a TB patient with their surgical mask at Zomba Police Hospital

6. Operations Research

There was no operations research planned in year 2; these are planned for APA3 (3 studies)

Title of OR study	Local partners involved in study	Implementation Status	Key findings	Dissemination

7. Key Challenges during Implementation and Actions to Overcome Them

Challenge	Actions to overcome challenges
Technical	
Overlapping of CTB and Global Fund activities	CTB and GF through NTP held a workshop to harmonize the work plans and are coordinating and collaborating at national, zonal and district level during the planning and implementation of the activities.
Lack of training curricula for some of the trainings	CTB to support NTP in revision of training curricula for all cadres on key focus areas such as TB/HIV management training for HCW and Prison providers
The shortage of TB microscopy sites has contributed to low case detection	CTB to support GF in the expansion of TB microscopy sites.
Knowledge gap of TB among HCW	CTB conducted trainings for Health Surveillance Assistants (HSAs), nurses and clinicians in TB/HIV management. CTB conducted supervision and mentorship as another means of addressing the knowledge gap.
Weak systems within the 6 ICF/ECF sites such as passive case finding, lack of TB-related health talks and IEC materials, no spot sputum sample submission	CTB hired two teams to intensify case finding in ART clinics and enhance case finding at outpatient department (OPD). CTB strengthened the health systems through active engagement of the DHO and facility leadership in identifying needs and acting on them, including patient triaging, fast-tracking for diagnosis and reinstating of health talks in patient waiting areas; provision of IEC materials; reinstating the submission of on-spot sputum samples, training and mentorship of HCW and HSAs.
Poor documentation in the recording tools	CTB conducted trainings in data management for different cadres that included ART Clerks, Ward Clerks, Patient Attendants and Microscopists who are responsible for documentation in the various recording tools at facility level.
No or few functional GeneXpert modules in some health centers with high TB burden in the catchment population	CTB procured and installed GeneXpert machines in 3 district facilities namely Bwila Hospital, QECH and Area 25 Health Centre and also supported installation of machines provided to the NTP through TB CARE II to 3 facilities including Dowa, Ntchisi and Chitipa.
Inadequate maintenance of GeneXpert machines	Comprehensive training of lab personnel on GeneXpert machines. Mentoring of Xpert sites on proper maintenance.

Challenge	Actions to overcome challenges
Technical	
Non-functionality of the NTRL	CTB has been supporting the renovation of the NTRL, which works expanded during the year and will now be completed by February 2017. In the mean time CTB has assisted by sending staff to Mzuzu laboratory to process the DST and culture sputum samples.
Limited human resources for laboratory interventions in the CTB project	To recruit one additional lab personnel in the project in APA3.
Lack of 2nd line DST for RR/MDR-TB cases	To send samples for 2nd line DST at SRL. To build local capacity of 2nd line DST during DRS
Low utilization of GeneXpert across the country	Revise the Xpert algorithm to include all presumptive TB cases.
Insufficient technical resources for the project (3 Zonal TB Advisers covering all 5 zones)	Recruitment to be planned with additional funding
Frequent electricity blackouts countrywide leading to interruption in the processing of samples	CTB has supplied inverters and batteries to laboratories with GeneXpert platforms to support the laboratory work. CTB also procured FM with solar panels and is also investigating the use of solar panels in some laboratories supporting ICF/ECF activities.
Administrative	
Shortage of admin staff due to delay in recruitment and high volume of field level activity implementation	CTB is hoping to hire additional staff in year 3 to enable proper administration of field level activities.

8. Lessons Learnt/ Next Steps

1. Good Coordination and collaboration at all levels: From the start of the project, NTP offered office space to CTB key staff (Country Director, Diagnostic Network Advisor and Monitoring and Evaluation Advisor) for easy collaboration and coordination of activities. This has played a significant role as both NTP and CTB staff were well informed of CTB and GF activities throughout the year. The sharing of offices provided an opportunity for both parties to share experiences as well. Also the CTB Zonal TB Advisers are housed in NTP Zonal offices, which has resulted in good implementation of activities. Furthermore, in order to strengthen the collaboration between NTP and CTB:

- There was a planning meeting to merge the GF and CTB activities into a consolidated work plan;
- CTB supports NTP in entering national level data, which is collected during joint TB/HIV supervision visits. This collaboration has enhanced good sharing of data between the two partners;
- CTB has hired a Procurement and Supply Management Technical Advisor who works directly and is answerable to the NTP Program Manager

From quarter 4, NTP has been granted a World Bank project for TB in mines and some of its representatives are also housed in the NTP offices. CTB anticipates that this coordination will continue with World Bank project as well. Lessons learnt are that there is increasing ownership of the project by NTP counterparts, which can lead to sustainability once projects phase out. Also, good coordination and

collaboration between partners will lead to timely and quality implementation of activities and the project aims to continue this networking in year 3.

2. Involvement of lower cadre HCWs can improve case detection: Lower cadre HCW such as Patient Attendants and Ward Clerks are key in improving case detection. During a baseline assessment that was conducted jointly by CTB and NTP in quarter 2, it was discovered that Mangochi District Hospital was innovative in that it was using non-HCWs in the collection of sputum from the wards as well as documentation of presumptive TB cases in the Chronic Cough Registers. It was found that some clients may be missed within the hospital through OPDs, ART clinics etc. and may end up in the wards undiagnosed. Because of this missed opportunity, the hospital adopted the use of Patient Attendants and Ward Clerks in finding these missed cases in the wards. In order to adopt this innovation and good practice, CTB supported NTP through training these cadres in TB Management such as screening for TB, collection of sputum and documentation. CTB also trained ART Clerks and OPD Clerks in the same issues so that at each entry point, no opportunity to detect cases is missed.

Following these trainings, the Clerks have since introduced Chronic Cough Registers in the various sites where the register was not there before (e.g. ART clinics, OPD, Male/Female Wards) and there has been a notable increase in the number of presumptive TB cases. The project has learnt that through the use of these lower cadres, case detection can improve. Moving into year 3, CTB will train more of such cadres, supervise and mentor them.

3. Presence of CTB Zonal TB Advisers: The presence of CTB Zonal TB Advisers at the NTP zonal offices is an asset to the project as it ensures representation of CTB at that level and also strengthens collaboration with Ministry of Health and NTP counterparts. The central level staff was able to follow up implementation of project activities through the Zonal TB Advisers and hence provided some input/suggestions and identified opportunities on the implementation strategies. Because of their presence, when the project was overwhelmed with activities due to late recruitment and shortage of staff, the Zonal Advisers went to lower levels of implementation. CTB has learnt that the Zonal Advisers play a significant role in collaborative and quality implementation of activities by partners.



CTB Zonal Adviser, Patrick Gomani (on the right), helping MoH and NTP district staff setting up a tent in preparation of World TB Day celebrations in Balaka district funded by CTB

Annex I: Year 2 Results on Mandatory Indicators as well as National Data on the Number of pre-/XDR-TB Cases Started on Bedaquiline or Delamanid

2.1.2 A current national TB laboratory operational plan exists and is used to prioritize, plan and implement interventions.	National APA 2	CTB APA 2	CTB APA 2 investment	Additional Information/Comments
Score as of September 30, 2016	1	N/A	Substantial	NTP with support from CTB reviewed the National TB laboratory operational plan. The first review meeting was done in salima in June, 2016. The National TB laboratory plan will be finalized in APA3.
2.2.6 Number and percent of TB reference laboratories (national and intermediate) within the country implementing a TB-specific quality improvement program i.e. Laboratory Quality Management System	National APA 2	CTB APA 2	CTB APA 2 investment	Additional Information/Comments
Number and percent as of September 30, 2016	0% (0/2)	N/A	Substantial	There are two reference labs with C/DST capacity (National and intermediate). LQMS is implemented in all these laboratories. In terms of scoring, the NTRL is zero, whilst the Mzuzu reference lab has not been assessed.

2.2.7 Number of GLI-approved TB microscopy network standards met	National APA 2	CTB APA 2	CTB APA 2 investment	Additional Information/Comments
Number of standards met as of September 30, 2016	6 out of 11 standards met	N/A	Substantial	Standard 3, Standard 4, Standard 6, Standard 7 Standard 9 and standard 11.
2.3.1 Percent of bacteriologically confirmed TB cases who are tested for drug resistance with a recorded result.	National 2015	CTB 2015	CTB APA 2 investment	Additional Information/Comments
Percent (new cases) , include numerator/denominator				It has been a challenge obtaining this data during the year mainly because of the paper-based system. The NTRL is undergoing some renovations and samples have been going to Mzuzu reference laboratory for processing. In due course, there has been a hiccup of documentation. CTB will support the NTP to implement GxAlert which will be more efficient and reliable in obtaining this data from APA3.
Percent (previously treated cases) , include numerator/denominator				
Percent (total cases) , include numerator/denominator				
3.1.4. Number of RR-TB or MDR-TB cases notified	National APA 2	CTB APA 2	CTB APA 2 investment	Additional Information/Comments
Total 2015	93	Data for CTB geographical areas not available	Substantial	This is national data. The reporting tool does not capture this data by district. NTP recently
Jan-Mar 2016				

Apr-June 2016	35 (Combined data for 2 quarters)			reviewed its recording and reporting tools to include MDR TB cases by district. Note that data for July - September will be collected through Integrated TB/HIV supervision planned to start from the second week of October.
Jul-Sept 2016				
To date in 2016	0	0		
3.2.1. Number and percent of TB cases successfully treated (all forms) by setting (i.e. private sector, pharmacies, prisons, etc.) and/or by population (i.e. gender, children, miners, urban slums, etc.).	National 2014 cohort	CTB 2014 cohort	CTB APA 2 investment	Additional Information/Comments
Number and percent of TB cases successfully treated in a calendar year cohort	Getting from WHO	86% (12210/14097) CTB geographical areas	Substantial	Treatment success rate is routinely tracked by NTP. Currently, this indicator cannot be disaggregated for treatment outcomes by setting and populations for the cohort under review. The revised R&R tools (introduced in April 2016) include outcomes for PLHIV and children. The first disaggregated outcome data will be available for the patient cohort registered for TB treatment from next year (2017)
3.2.4. Number of patients started on MDR-TB treatment	National APA 2	CTB APA 2	CTB APA 2 investment	Additional Information/Comments
Total 2015	65		Moderate	

Jan-Mar 2016	23 (Combined data for two quarters (Jan to June,2016)	16 (Combined data for two quarters (Jan to June,2016)		This is national data. The reporting tool does not capture this data by district. NTP recently reviewed its recording and reporting tools to include MDR TB cases by district. Note that data for July - September will be collected through Integrated TB/HIV supervision planned to start from the second week of October.
Apr-June 2016				
Jul-Sept 2016				
To date in 2016	0	0		
3.2.7. Number and percent of MDR-TB cases successfully treated	National 2013 cohort	CTB 2013 cohort	CTB APA 2 investment	Additional Information/Comments
Number and percent of MDR-TB cases successfully treated in a calendar year cohort	Getting from WHO	40% (6/15) CTB area	Moderate	15 cases were initiated on SLD of whom 6 (40 %) were successfully treated.
5.2.3. Number and % of health care workers diagnosed with TB during reporting period	National 2015	CTB 2015	CTB APA 2 investment	Additional Information/Comments
Number and percent reported annually	Data not available at national level	1.7% (58/3377) Baseline Assessment done by CTB in its 15 priority districts.	Moderate	The current NTP recording and reporting tools does not capture this indicator. However, the baseline assessment which was done by CTB and NTP in the 15 priority districts found that 1.7% of Health Care workers were diagnosed with TB (58/3377)

6.1.11. Number of children under the age of 5 years who initiate IPT	National 2015	CTB 2015	CTB APA 2 investment	Additional Information/Comments
Number reported annually	1,947	1,485	Moderate	In 2015, 1,485 Children under the age of 5 were put on IPT in 15 CTB geographical areas. At national level 1,947 children under the age of 5 were put on IPT.
7.2.3. % of activity budget covered by private sector cost share, by specific activity	National APA 2	CTB APA 2	CTB APA 2 investment	Additional Information/Comments
Percent as of September 30, 2016 (include numerator/denominator)	N/A	0%	None	There was no investment from CTB in this area in APA2
8.1.3. Status of National Stop TB Partnerships	National APA 2	CTB APA 2	CTB APA 2 investment	Additional Information/Comments
Score as of September 30, 2016	N/A	N/A	None	The status of National Stop TB partnership was not assessed in this reporting period. This will be done in APA4
8.1.4. % of local partners' operating budget covered by diverse non-USG funding sources	National APA 2	CTB APA 2	CTB APA 2 investment	Additional Information/Comments
Percent as of September 30, 2016 (include numerator/denominator)	N/A	Not available	None	There was no investment from CTB in this area in APA2.
8.2.1. Global Fund grant rating	National APA 2	CTB APA 2	CTB APA 2 investment	Additional Information/Comments

Score as of September 30, 2016	B1 (Average)	N/A	Substantial	Late disbursements of funds is affecting the timely implementation of GF activities.
9.1.1. Number of stock outs of anti-TB drugs, by type (first and second line) and level (ex, national, provincial, district)	National APA 2	CTB APA 2	CTB APA 2 investment	Additional Information/Comments
Number as of September 30, 2016	0	0	Substantial	There has not been any stock out reported in this reporting period
10.1.4. Status of electronic recording and reporting system	National APA 2	CTB APA 2	CTB APA 2 investment	Additional Information/Comments
Score as of September 30, 2016	1	N/A	Substantial	Electronic reporting to national level but not case based or real time. Consultants from KNCV - TB Foundation assessed the feasibility of implementing a case-based electronic recording and reporting (ERR) system in APA1 Q4. The consultants visited Malawi again from 30 May-3 June 2016 where a draft road map for

				implementation of ERR system was defined.
10.2.1. Standards and benchmarks to certify surveillance systems and vital registration for direct measurement of TB burden have been implemented	National APA 2	CTB APA 2	CTB APA 2 investment	Additional Information/Comments
Yes or No as of September 30, 2016	0	N/A	None	The surveillance system have not been assessed in this reporting period
10.2.6. % of operations research project funding provided to local partner (provide % for each OR project)	National APA 2	CTB APA 2	CTB APA 2 investment	Additional Information/Comments
Percent as of September 30, 2016 (include numerator/denominator)	N/A	0	None	There was no investment from CTB in operation research in APA2.
10.2.7. Operational research findings are used to change policy or practices (ex, change guidelines or implementation approach)	National APA 2	CTB APA 2	CTB APA 2 investment	Additional Information/Comments

Yes or No as of September 30, 2016	N/A	N/A	None	There was no operation research in APA2.
11.1.3. Number of health care workers trained, by gender and technical area	CTB APA 2		CTB APA 2 investment	Additional Information/Comments
			Substantial	In APA2, CTB made substantial investment in capacity building of health care workers in different areas of competencies as shown below:
	# trained males APA 2	# trained females APA 2	Total # trained in APA 2	Total # planned trainees in APA 2
1. Enabling environment	838	530	1368	1800
2. Comprehensive, high quality diagnostics	61	16	77	77
3. Patient-centered care and treatment	0	0	0	0
4. Targeted screening for active TB	0	0	0	0
5. Infection control	61	15	76	76
6. Management of latent TB infection	0	0	0	0
7. Political commitment and leadership	0	0	0	0
8. Comprehensive partnerships and informed community involvement	76	32	108	108
9. Drug and commodity management systems	0	0	0	0

10. Quality data, surveillance and M&E	584	315	899	950
11. Human resource development	0	0	0	0
TB/HIV Supervision Supervisors Training	38	8	46	46
Other (explain)	0	0	0	0
Grand Total	1658	916	2574	3060
11.1.5. % of USAID TB funding directed to local partners	National APA 2	CTB APA 2	CTB APA 2 investment	Additional Information/Comments
Percent as of September 30, 2016 (include numerator/denominator)	N/A	0		USAID funding was not directed to any partner in this reporting period.

Year/Quarter	Number of pre-/XDR-TB cases started on BDQ nationwide	Number of pre-/XDR-TB cases started on DLM nationwide	CTB APA 2 investment	Additional Information/Comments
Total 2014	0	0	None	No XDR-TB case was reported during this reporting period.
Total 2015	0	0		
Jan-Mar 2016	0	0		
Apr-Jun 2016	0	0		
Jul-Aug 2016	0	0		
To date in 2016	0	0		

Number and percent of cases notified by setting (i.e. private sector, prisons, etc.) and/or population (i.e. gender, children, miners, urban slums, etc.) and/or case finding approach (CI/ACF/ICF) (3.1.1)							
		Reporting period					CTB APA 2 investment
		Oct-Dec 2015	Jan-Mar 2016	Apr-Jun 2016	Jul-Sept 2016	Cumulative Year 2	
Overall CTB geographic areas	TB cases (all forms) notified per CTB geographic area (<i>List each CTB area below - i.e. Province name</i>)						
	Balaka	102	124	94		320	
	Blantyre	787	631	672		2,090	
	Chikhwawa	185	206	210		601	
	Karonga	61	59	45		165	
	Kasungu	47	50	50		147	
	Lilongwe	903	916	999		2,818	
	Machinga	88	169	86		343	
	Mangochi	201	215	178		594	
	Mulanje	123	136	131		390	
	Mwanza	70	69	76		215	
	Mzimba	228	270	226		724	
	Nsanje	110	135	141		386	
	Phalombe	55	55	77		187	
	Salima	83	100	91		274	
	Zomba	189	227	261		677	
	TB cases (all forms) notified for all CTB areas	3,232	3,362	3,337		9,931	
	All TB cases (all forms) notified nationwide (denominator)	3,912	4,123	4,077		12,112	
	% of national cases notified in CTB geographic areas	82,6%	81,5%	81,8%		82,0%	
Intervention (setting/population/approach)							

Reported by prisons	CTB geographic focus for this intervention	15 CTB priority districts				Substantial			
	TB cases (all forms) notified from this intervention	22	69	67					
	All TB cases notified in this CTB area (denominator)	2,107	1,775	1,932					
	% of cases notified from this intervention	1%	4%	3%					
Intensified case finding (ICF) (e.g. health facility-based case finding)	CTB geographic focus for this intervention	15 CTB priority districts							
	TB cases (all forms) notified from this intervention	3,232	3,362	3,337				9,931	
	All TB cases notified in this CTB area (denominator)	3,232	3,362	3,337				9,931	
	% of cases notified from this intervention	100%	100%	100%				100%	
Reported by private providers (i.e. non-governmental facilities)	CTB geographic focus for this intervention	15 CTB priority districts						0	
	TB cases (all forms) notified from this intervention	581	731	684				1,996	
	All TB cases notified in this CTB area (denominator)	3,232	3,362	3,337				9,931	
	% of cases notified from this intervention	18%	22%	20%				20%	
Children (0-14)	CTB geographic focus for this intervention	15 CTB PRIORITY DISTRICTS						Substantial	
	TB cases (all forms) notified from this intervention	302	314	322		938			
	All TB cases notified in this CTB area (denominator)	3232	3362	3337		9931			
	% of cases notified from this intervention	9	9	10	#DIV/0!	9			

Annex II: Status of EMMP activities

Year 2 Mitigation Measures	Status of Mitigation Measures	Outstanding issues to address in Year 3	Additional Remarks
Education, technical assistance, training, etc. Education, technical assistance and training about activities that inherently affect the environment include discussion prevention and mitigation of potential negative environmental effects.	N/A	Nil	There were no educational and training activities that had any adverse impact on the environment.
Public health commodities CTB will ensure proper procurement of lab equipment and reagents, X-ray machines and other items, which will be delivered directly to 1 central and 5 zonal storage facilities. Although the responsibility for proper storage and distribution to the intermediate/peripheral levels lies with the NTP, CTB will advise the NTP on the proper storage based on the information provided on the manufacturer's Materials Safety Data Sheet as well as WHO's <i>Safe Management of Waste from Health-care Activities</i> (http://www.who.int/water_sanitation_health/medicalwaste/wastemanag/en/). Additionally, implementing partners will follow all host country laws and regulations and also be guided by NTP. The partners are NTP and PEPFAR implementing partners. Supplemental information may be found in the Environmental Sector Guidelines at http://www.usaidgems.org/sectorGuidelines.htm CTB will advise the Government (i.e. MoH/NTP) to follow the guidelines provided in the <i>Guidelines for Small-Scale Activities in Africa</i> for proper packaging and disposal of all public health commodities other than pharmaceutical drugs.	CTB ensured proper procurement and storage of lab and X-ray equipment and supplies. CTB ensured that NTP and health facilities are aware of how to properly store, use and dispose lab reagents according to manufacturer's Material Safety Data Sheets. Furthermore, sites that received backup power batteries were instructed according to manufacturer's package inserts on how to properly dispose out-of-use batteries. CTB and NTP also involved the Ministry of Health Radiology department who have inspected the two mobile X-ray machines and approved. The machines which is digital will be operated as per protocol agreed to by NTP and CTB	Nil	In APA3 CTB will support the development of a national safety manual for TB labs. The manual will provide a clear and standard guide on how labs can safely store and dispose any TB lab commodities
Medical waste For health facilities being supported by CTB, the project will obtain and be guided by the country's non-medical and medical waste management regulations and procedures if	CTB supported the updating of the NTP Infection Control guidelines. In these guidelines clear management	To finalize the Laboratory Biosafety Manual for NTRL and Mzuzu culture labs.	Nil

Year 2 Mitigation Measures	Status of Mitigation Measures	Outstanding issues to address in Year 3	Additional Remarks
<p>available with the Government. If not then CTB will be guided by the NTP. CTB will support training in clinical waste management and ensure that it is integrated into training programs and NTP guidelines. Training material will align with either the <i>Environmental Guidelines for Small-Scale Activities in Africa</i> or the national regulations and procedures for medical waste.</p> <p>For the supported facilities that have biosafety cabinets for microscopy as well as the two labs that perform culture and phenotypic drug susceptibility testing, CTB will provide technical assistance to ensure that the biosafety cabinets are timely validated and recertified. CTB has serviced all biosafety cabinets it is responsible for thus ensuring quality and optimal services. Furthermore, CTB will work with NTP to ensure that all infectious waste generated in each lab (central, district and some of the peripheral labs) is autoclaved before disposal. At lower level facilities where autoclaves are not available, waste will be properly packaged and incinerated.</p> <p>During supportive supervision visits, management and disposal of medical waste will be discussed and checked; when necessary corrections will be made. If PEPFAR checklist doesn't include waste management the project will work towards ensuring this is included in the and reviewers trained accordingly.</p>	<p>of medical waste was clearly stipulated. CTB also assisted in the printing of these guidelines which were distributed to users. CTB also supported training on infection control and prevention. This training also included a component on waste management in health facilities.</p> <p>CTB also supported the NTP on the maintenance service of biosafety cabinets in microscopy and culture labs by a reputable service provider. CTB also assisted the NTRL on the updating of their Laboratory Safety Manual</p> <p>CTB also supported supportive supervision to peripheral sites. During these supervisions, practices on medical waste management were assessed and improvement plans were recommended and followed up</p>	<p>To develop and orient lab personnel on the national biosafety manual for TB laboratories</p>	
<p>Small scale construction CTB will review any minor renovation plans prior to implementation to ensure compliance with environmentally sound rehabilitation practices as laid out in the <i>Small Scale Construction chapter of the USAID Environmental Guidelines for Small-Scale Activities in Africa</i>. For example, no lead paint will be used and excess materials will be recycled or disposed</p>	<p>In APA2 CTB supported minor renovations at the NTRL. These were subcontracted to local and reputable contractors. During the renovations CTB and NTP officers conducted regular visits to ensure that</p>	<p>Through the support from CTB, the NTRL will be upgraded to a BSL3 to meet the minimum WHO infrastructure and safety requirements. This is expected to be</p>	<p>Nil</p>

Year 2 Mitigation Measures	Status of Mitigation Measures	Outstanding issues to address in Year 3	Additional Remarks
<p>of in an environmentally sound manner. For any TB laboratory where culture and phenotypic drug susceptibility testing is done, rooms should be built with negative pressure to mitigate the risk of cross contamination or occupational health –related TB infection. CTB will provide technical assistance to ensure that the negative pressure systems are timely serviced by a reputable service provider</p> <p>The Government and CTB (or a contracted architect hired to supervise the project) will conduct regular site inspections to ensure the public health standards are met and in line with national policy/regulations.</p> <p>CTB and the Government will conduct regular (sometimes random) site visits to ensure the minimum environmental requirements are as indicated in the official documents</p> <p>Training and information in use of incinerators and proper handling of clinical waste will be included in relevant activities, including supportive supervision visits.</p>	<p>the minimum environmental requirements were met. There was no environmentally adverse material used. The contractors collected any excess material or waste and disposed in designated landfills routinely monitored by the local municipality.</p>	<p>completed by Feb 2017. A reputable company, AFMS, will be used for the proposed works. Once the renovations are completed, experts from WHO and SRL will be invited to inspect and certify the NTRL as meeting the WHO minimum requirements</p> <p>CTB will also support the replacement of BSL3 lab doors and minor repairs at Mzuzu Central Hospital. This expected to be completed before December 2016</p>	